In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: November 24, 2020

BRADLEY GROW,	*	No. 16-13V
Petitioner,	*	Special Master Sanders
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Decision; Entitlement; Ruling on the Record; Influenza ("Flu") Vaccine; Brachial Neuritis; Parsonage Turner Syndrome ("PTS").
Respondent.	*	

Lisa A. Roquemore, Law Office of Lisa A. Roquemore, Rancho Santa Margarita, CA, for Petitioner.
Catherine E. Stolar, United States Department of Justice, Washington, DC, for Respondent.

DECISION ON ENTITLEMENT[1]

On January 4, 2016, Bradley Grow ("Petitioner") filed a petition for compensation in the National Vaccine Injury Compensation Program ("the Program").[2] ECF No. 1. Petitioner alleged that the influenza ("flu") vaccine he received on January 14, 2013, caused him to develop brachial neuritis, also known as Parsonage Turner Syndrome[3] ("PTS"). *Id.* at 4. For the reasons discussed herein, I deny Petitioner's claim and find that Petitioner is not entitled to compensation.

[1] This Decision shall be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet**. In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted Decision. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be deleted from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755 ("the Vaccine Act" or "Act"). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

[3] Brachial neuritis/Parsonage Turner Syndrome is another term for neuralgic amyotrophy, which "is an uncommon disorder of the peripheral nervous system characterized by the sudden onset of extreme pain in the upper extremity followed by rapid multifocal motor weakness and atrophy and a slow recovery in months to years." *Dorland's Illustrated Medical Dictionary* 1263, 1391 (32nd ed. 2012) [hereinafter "*Dorland's*"].

I. Procedural History

Petitioner filed his petition on January 4, 2016. ECF No. 1. The next day, Petitioner submitted several exhibits consisting of medical records from several of his treating physicians. Pet'r's Exs. 1–9, ECF Nos. 5-1–5-9. Petitioner filed his first statement of completion on January 19, 2016. ECF No. 9. Thereafter, Petitioner submitted additional medical records on January 27, 2016, April 18, 2016, and May 2, 2016. *See* Pet'r's Exs. 10–12, ECF Nos. 10, 13, 15.

On April 4, 2016, Respondent filed a status report advising the Court that this claim was appropriate for settlement and requesting that Petitioner provide a demand. ECF No. 12. In response to the Court's April 20, 2016 scheduling order, on May 20, 2016, Petitioner filed a status report advising the Court as to the progress of settlement discussions between the parties. ECF Nos. 14, 16. The parties continued to engage in settlement discussions throughout 2016 and updated the Court accordingly. *See* ECF Nos. 17–19, 21, 25, 27–29. In furtherance of the parties' settlement discussions, Petitioner submitted additional medical records. Pet'r's Exs. 13–18, ECF Nos. 20, 24, 26. On November 2, 2016, the Court issued a 15-Week Stipulation Order indicating the parties had reached a tentative settlement agreement and requesting a status report from Respondent by February 14, 2017. ECF No. 29. Yet, on February 1, 2017, Respondent submitted a status report stating, "the settlement referenced by the 15-Week Stipulation Order of November 2, 2016, will not be approved," and requesting a status conference to discuss further proceedings. ECF No. 30. The status conference was scheduled for February 13, 2017. Non-PDF Order, docketed Feb. 9, 2017.

On February 9, 2017, the same day the Court scheduled the status conference, the parties filed a joint status report requesting that the status conference be removed from the calendar because "the parties agreed that they would recommence settlement discussions." ECF No. 31. On February 10, 2017, the Court cancelled the status conference. Scheduling Order at 1, ECF No. 32. The parties filed a joint status report regarding the progress of their settlement discussions on March 22, 2017. ECF No. 33. The parties indicated they would like a status conference to discuss how to proceed. *Id.* A status conference was held on March 30, 2017, whereby the parties expressed that their settlement discussions were at an impasse but that they were not interested in mediation. Scheduling Order at 1, ECF No. 35. Respondent was ordered to file his Rule 4(c) Report by no later than May 2, 2017. *Id.* at 2.

Respondent filed his Rule 4(c) Report on May 2, 2017. Resp't's Report, ECF No. 36. Respondent argued that the petition should be dismissed because Petitioner did not establish that he suffered PTS as a result of the flu vaccine he received on January 14, 2013. *Id.* at 1. Respondent further argued Petitioner failed to "proffer a medical theory sufficient to establish a logical cause and effect relationship between the vaccination and his alleged injury." *Id.* at 11.

On June 8, 2017, Petitioner filed an expert report from Dr. Eric Gershwin, M.D., and fifty-two pieces of medical literature. Pet'r's Exs. 23–72, ECF Nos. 41–46. Respondent filed a responsive expert report from Dr. Thomas Leist, M.D., PhD, together with two pieces of medical literature on October 3, 2017. Resp't's Exs. A, A-1, A-2, B, ECF Nos. 49-1–49-4. On November 21, 2017, Petitioner filed his first supplemental expert report from Dr. Gershwin. Pet'r's Exs. 80–82, ECF Nos. 51-1–51-3. The same day, Petitioner submitted additional evidence regarding the

judgment of dissolution of his marriage. Pet'r's Ex. 83, ECF No. 52. On December 14, 2017, Petitioner filed his own declarative response to Respondent's expert report. Pet'r's Ex. 84, ECF No. 53. Respondent filed a supplemental expert report from Dr. Leist, along with supporting literature, on February 27, 2018. Resp't's Exs. C, C-1, C-2, ECF Nos. 56-1–56-3. In response, Petitioner submitted his second supplemental expert report from Dr. Gershwin, along with supporting literature, on March 20, 2018. Pet'r's Exs. 85–88, ECF Nos. 58-1–58-4.

I held a telephonic status conference with the parties on March 29, 2018. *See* Minute Entry, docketed Mar. 30, 2018. During the conference, Respondent noted his concerns regarding the five-month post-vaccination onset issue in this case and reiterated his view that Petitioner's PTS began when he complained of muscle weakness. *See* Scheduling Order at 1, ECF No. 59. I ordered Petitioner to submit a status report outlining specific medical literature that addressed whether pain heralds the onset of PTS or if muscle weakness is a necessary condition for diagnosis, *id.*, which Petitioner filed on April 3, 2018. ECF No. 60. Respondent filed a status report on May 16, 2018, in which he stated that Dr. Leist's supplemental expert report "adequately addressed all of the points raised by [P]etitioner's counsel in [P]etitioner's status report of April 3, 2018." ECF No. 61. Respondent contended that Dr. Leist had already shown that Petitioner's injury does not fit the normal progression of PTS with pain being the heralding event but instead presents with weakness at the time of onset. *Id*. Respondent also requested that an entitlement hearing be scheduled. *Id.*

I held another telephonic status conference with the parties on May 30, 2018. *See* Minute Entry, docketed May 30, 2018. During the conference, I noted that because the issues in contention are well defined, this case may be appropriate for a ruling on the record. *See* Scheduling Order at 1, ECF No. 62. On September 6, 2018, Petitioner filed a motion for a ruling on the record, and Respondent filed his response on October 22, 2018. ECF Nos. 64, 66. Petitioner filed his reply on November 1, 2018. ECF No. 67.

Upon my thorough review of Petitioner's medical records, I determined there were inconsistencies regarding Petitioner's description of his initial pain and the onset time he reported to his treating physicians. *See* Scheduling Order at 1, ECF No. 71. I also required more information from Petitioner's expert, Dr. Gershwin, regarding "the causation theory and how it applies to Petitioner's PTS[.]" *Id.* Accordingly, on July 9, 2019, I ordered Petitioner to file an affidavit that addressed these discrepancies, along with a concise supplemental expert report from Dr. Gershwin explaining the role of the vaccine in the development of Petitioner's PTS. *Id.* On August 8, 2019, Petitioner filed his third supplemental expert report from Dr. Gershwin, along with four pieces of supporting literature. Pet'r's Exs. 90–94, ECF Nos. 72-1–72-5. The same day, Petitioner submitted his supplemental affidavit regarding the discrepancies in his medical records. Pet'r's Ex. 95, ECF No. 73. On October 20, 2019, Respondent filed a responsive supplemental expert report from Dr. Leist, along with a supporting exhibit, and an updated exhibit list. Resp't's Exs. D, D-1, ECF Nos. 75-1–75-2, 76. On November 26, 2019, Petitioner filed his fourth supplemental expert report from Dr. Gershwin, along with a supporting exhibit, that mostly reiterated the assertions made in his previous reports. Pet'r's Exs. 96–97. ECF Nos. 77-1–77-2.

This matter is now ripe for consideration.

II. Evidence

A. Relevant Medical History

Petitioner is a fifty-year-old man whose medical history prior to vaccination is notable for shoulder pain, back pain, and carpal tunnel syndrome. *See generally* Pet'r's Exs. 1, 3, ECF Nos. 5-1, 5-3. Petitioner was seen by Dr. Peter Grant, M.D., a physical medicine and rehabilitation specialist, on January 26, 2009 for a history of "very severe and chronic carpal tunnel syndromes on the right greater than left sides[,]" for which he had "bilateral carpal tunnel decompressions" with "good results." Pet'r's Ex. 3 at 1.

On April 5, 2010, Petitioner saw nurse practitioner ("N.P.") Raymond Millette, in place of a primary care physician, at Millette Family Medicine for "moderate back and shoulder pain." Pet'r's Ex. 1 at 1. At that time, Petitioner denied numbness in both arms. *Id.* Petitioner described his symptoms as "gradual in onset," with an "aching, a throbbing, and an irritated quality." *Id.* He also stated that the "onset of [his] condition may have been associated with a sports[] injury" and that it was "aggravated by lifting and movement," although the use of NSAIDs,[4] marijuana, and pain medication provided some relief. *Id.* Petitioner was diagnosed with muscle spasms and myalgia and was prescribed methadone.[5] *Id.* at 2.

Petitioner visited N.P. Millette again on September 14, 2010 for the same "moderate back and shoulder pain." *Id.* at 4. Petitioner reported that he had been seeing a chiropractor, "that has been helpful," and that he experienced "left upper scapular muscle tension" when he was busy at work. *Id.* He also reported that his pain, which he rated as a nine on a scale from one to ten, with ten being very painful, decreased to a six or seven after using marijuana and pain medication. *Id.* An examination revealed mid-thoracic and lumbar spine pain, as well as left upper trapezius[6] and scapular[7] tension. *Id.* at 5. The diagnoses remained unchanged and Petitioner was again prescribed methadone. *Id.* Petitioner saw N.P. Millette two-to-three times annually during 2011 and 2012 for the same complaints of moderate aching and throbbing back and shoulder pain. *See id.* at 13–21, 24–25.

On January 9, 2013, Petitioner again saw N.P. Millette for "moderate back and shoulder pain" that was "aggravated by lifting and movement." *Id.* at 26. He reported that his pain was a seven or eight on the pain scale, dropping to a five or six after using marijuana and pain medication. *Id.* Petitioner also reported "foot pain that seem[ed] to be getting worse" and "denie[d experiencing] numbness in [the] left arm and numbness in [the] right arm." *Id.* The diagnoses remained unchanged, with the addition of "pain in joint, ankle and foot." *Id.* at 27.

On January 14, 2013, per a prescription record, Petitioner received the flu vaccine in

---

[4] The term NSAIDs stands for nonsteroidal anti-inflammatory drugs. *Dorland's* at 1293.

[5] Methadone is "a synthetic opioid analgesic, possessing pharmacologic actions similar to those of morphine and heroin[.]" *Dorland's* at 1146.

[6] The trapezius muscle "elevates [the] shoulder, rotates [the] scapula to raise [the] shoulder in abduction of [the] arm, [and] draws [the] scapula backward." *Dorland's* at 1212.

[7] The scapula is "the flat, triangular bone in the back of the shoulder . . . called also *shoulder blade*." *Dorland's* at 1673 (emphasis in original).

question, but the prescription record does not indicate the site of vaccination. Pet'r's Ex. 1 at 29. A month later, on February 12, 2013, Petitioner called his chiropractor, Scott Thorsen, for "upper back and shoulder pain" that Petitioner estimated had begun one week previously. Pet'r's Ex. 2 at 1, 3, ECF No. 5-2. Petitioner visited his chiropractor on February 14, 2013. *Id.* Petitioner reported that he had "received treatment from another chiropractor without much improvement" and that he experienced "moderately severe constant upper back pain on the right." *Id.* at 1. He also reported that he experienced "frequent moderately severe stiffness with burning, dull, and achy pain migrating to the posterior right upper shoulder and right deltoid area." *Id.* A "[s]pinal evaluation revealed a moderate degree of fixation at T3–T6, and a mild degree of restricted joint function at C5–C6." *Id.* A physical examination revealed "a moderate amount of muscle tightness in the [t]rapezius and [l]evator scapulae[8] bilaterally and [p]osterior shoulder girdle[9] muscles on the right[.]" *Id.* It also revealed "a severe degree of muscle tightness and stiffness in the [t]rapezius and [l]evator scapulae on the right and [t]horacic paraspinal muscles on the right was elicited." *Id.* The examination also showed "moderate pain and discomfort at T3 to T5 on the right and a mild degree of pain at T4 to T5 on the left." *Id.* A Hawkins–Kennedy impingement test[10] was positive bilaterally and Petitioner had reduced right-side range of motion ("ROM") with moderate pain. *Id.* Neurological tests were normal. *Id.* Petitioner was diagnosed with myofasciitis,[11] segmental/somatic dysfunction of the cervical and thoracic spine, and shoulder bursitis.[12] *Id.*

At a follow-up visit with Mr. Thorsen on February 19, 2013, Petitioner reported "noticeable improvement in the severity of the thoracic region on the right." *Id.* at 2. A physical examination revealed "a decrease in the degree of hypertonicity in the [t]rapezius and [l]evator scapulae on the right and [t]horacic paraspinal muscles on the right, and a moderate amount of muscle tightness in the [t]rapezius and [l]evator scapulae on the left and [p]osterior shoulder girdle muscles on the right." *Id.* Mr. Thorsen's assessment was that Petitioner's "condition is improved and responding normally to treatment." *Id.*

On July 8, 2013, nearly six months after his vaccination, Petitioner returned to N.P. Millette for weakness and loss of strength on his right side. Pet'r's Ex. 1 at 30. Petitioner indicated he had experienced these symptoms for the last two months. *Id*. He also complained of "moderate back and shoulder pain." *Id.* Petitioner reported that he had "been lifting weights and noticed his right peck [was] weak and wasting," and that he had experienced pain in both lower extremities "with radiation down the left leg to the knee." *Id.* An examination revealed mid-thoracic and lumbar

---

[8] The levator scapulae is the muscle that raises the scapula. *Dorland's* at 1207.

[9] The shoulder girdle is "a complex arrangement of bones, ligaments, muscles, and tendons," whose "primary function . . . is to give strength and range of motion to the arm." Andrew Chung, *Shoulder Structure, Function and Common Problems*, HEALTHPAGES.ORG, https://www.healthpages.org/anatomy-function/shoulder-structure-function-and-problems/ (last visited Sept. 9, 2020).

[10] The Hawkins–Kennedy impingement test "is commonly used to identify possible subacromial impingement syndrome." *Hawkins/Kennedy Impingement Test of the Shoulder*, PHYSIOPEDIA, https://www.physio-pedia.com/Hawkins_/_Kennedy_Impingement_Test_of_the_Shoulder (last visited Sept. 9, 2020).

[11] Myofasciitis is "inflammation of a muscle and its fascia, particularly of the fascial insertion of muscle to bone." *Dorland's* at 1223.

[12] Bursitis is defined as "inflammation of the bursa," which is "a sac or saclike cavity filled with a viscid fluid and situated at places in the tissues at which friction would otherwise develop." *Dorland's* at 262, 264.

spine pain, left upper trapezius muscle and scapular tension, bilateral foot pain, and right pectoral muscle wasting "with neuropathic pain, [and] positive straight leg r[aise.]" *Id.* at 31. Petitioner's previous diagnoses of muscle spasms, myalgia, and pain in joint, ankle and foot remained unchanged. *Id.* However, Petitioner was also diagnosed with low back pain and back pain with radiation. *Id.* N.P. Millette ordered further imaging and gave Petitioner a nine-day prescription of prednisone.[13] *Id.* at 31–32.

On October 17, 2013, Petitioner underwent CT myelograms[14] of the cervical and thoracic spine. *Id.* at 33. The cervical CT myelogram showed "mild diffuse disc bulges and mild to moderate uncovertebral spurring[15]" at C4–C5 and C5–C6, with mild narrowing of the thecal sac[16] at those levels. *Id.* The cervical CT myelogram revealed mild to moderate foraminal narrowing at C5 and C6. *Id.* It also highlighted "neural foraminal narrowing"[17] at the left C6 level. *Id.* The thoracic CT myelogram showed "mild to moderate focal left posterior lateral narrowing of the thecal sac at the T11–T12 disc level" caused by a "bony spur projecting into the spinal canal from the left T10 lamina[18] and T11 pedicle."[19] *Id.* at 35.

On December 2, 2013, Petitioner saw N.P. Millette for "moderate back and shoulder pain." *Id.* at 37. Petitioner reported that although he had not been lifting weights, the muscle wasting of his right shoulder and pectoral muscle had continued. *Id.* He was again diagnosed with low back pain, muscle spasms, and pain in joint, ankle and foot. *Id.* at 38. Petitioner was scheduled to see a pain specialist and was prescribed methadone. *Id.* at 37–38.

On December 9, 2013, Petitioner saw Dr. Joseph Savino, a pain specialist, for "[m]uscle loss over the right shoulder and anterior chest." Pet'r's Ex. 5 at 1, ECF No. 5-5. Petitioner reported that the previous "spring he awoke one morning with mild neck and mid[-]back pain that was extending into his right shoulder region[,]" which "was treated with chiropractics [sic] and eventually the pain resolved." *Id.* Petitioner also reported that he "ha[d] had progressive muscle loss affecting his right pectoralis[20] region, triceps, and deltoid regions[,]" but he "denie[d] any

---

[13] Prednisone is "a synthetic glucocorticoid derived from cortisone, administered orally as an anti[-]inflammatory and immunosuppressant." *Dorland's* at 1509.

[14] A myelogram is "a radiograph of the spinal cord." *Dorland's* at 1219.

[15] Uncovertebral spurring is "an abnormal bony projection" "pertaining to or affecting the uncinate processes of a vertebra." *Dorland's* at 1757, 2001.

[16] Thecal sac is sometimes referred to as "dural sac" and is "the portion of the spinal dura mater extending caudally from the level of the first or second lumbar vertebrae to the attachment at the filum terminale externum…and containing the lumbar cistern, cauda equina, cerebrospinal fluid, and filum terminale internum." *Dorland's* at 1660.

[17] Neural foraminal narrowing, also known as neural foraminal stenosis, "is a type of spinal stenosis [that] occurs when the small openings between the bones in [the] spine . . . narrow or tighten." *Neural Foraminal Stenosis: Overview*, HEALTHLINE, https://www.healthline.com/health/neural-foraminal-stenosis (last visited Sept. 23, 2020).

[18] Lamina is a term that "is often used alone to mean the lamina arcus vertebrae," i.e., "either of the pair of broad plates of bone flaring out from the pedicles of the vertebral arches and fusing together at the midline to complete the dorsal part of the arch and provide a base for the spinous process." *Dorland's* at 1000.

[19] The pedicle or pediculus arcus vertebrae is defined as "one of the paired parts of the vertebral arch that connect a lamina to the vertebral body." *Dorland's* at 1401.

[20] It is unclear whether the notes refer to the pectoralis major or the pectoralis minor. The pectoralis major

injury or known trauma[,]" stating that he was "in little to no pain at all." *Id.* The physical examination revealed that Petitioner had a full ROM in his neck, shoulders, upper and lower extremities bilaterally, and lumbar spine. *Id.* at 2. The examination also showed no pain or tenderness in the upper extremities and the thoracic and lumbar spine. *Id.* It also revealed "[n]o subacromial[21] or subdeltoid[22] bursa tenderness" or impingement signs. *Id.* A neurological examination showed that Petitioner had "atrophy of [his] right pectoralis major and triceps muscle groups." *Id.* Dr. Savino noted that Petitioner "ha[d] a build consistent with a weight lifter[,] demonstrating hypertrophy throughout both upper extremities." *Id.* He also noted that Petitioner's condition was "likely consistent with brachial plexitis[23] (Parsonage[]Turner [s]yndrome) or plexopathy.[24]" *Id.*

On February 4, 2014, Petitioner returned to Dr. Grant for an electromyogram ("EMG") [25] of the injured area. Pet'r's Ex. 3 at 1. Petitioner reported that his symptoms had begun approximately a year earlier "rather insidiously," with severe pain in the right periscapular and shoulder area. *Id.* He also reported that the pain had subsided "within a week or two" with chiropractic treatment. *Id.* He then noticed "some weakness in different areas of the chest and arm, as well as some atrophy," which had remained unchanged over the previous six to nine months. *Id.* A physical examination showed atrophy of the right pectoralis and triceps[26] muscles. *Id.* at 2. Deep tendon reflexes ("DTRs") [27] were "absent at the right triceps and 1+ at the left triceps" and both biceps.[28] *Id.* Muscle testing revealed right elbow and right wrist weakness with "some residual loss of sensation in [the] median [nerve] distribution bilaterally." *Id.* The EMG revealed "chronic, persistent, and severe denervation" of the pectoralis, triceps, and pronator teres[29] muscles on the right, with "a lesser amount of involvement in a[n] extensor carpi radialis longus[30] on the right." *Id.* "[S]ignificant neuropathic motor unit abnormalities" were observed in these muscles. *Id.* Dr. Grant's impressions were that the "[r]ight upper extremity denervation and neuropathic disease

---

is a "greater pectoral muscle" that "adducts, flexes, [and] rotates [the] arm medially." The pectoralis minor is a "smaller pectoral muscle" that "draws [the] shoulder forward and downward, [and] raises [the] third, fourth, and fifth ribs in forced inspiration." *Dorland's* at 1208.

[21] Subacromial means "inferior to the acromion," which is defined as "the lateral extension of the spine of the scapula, projecting over the shoulder joint and forming the highest point of the shoulder." *Dorland's* at 20, 1789.

[22] Subdeltoid means "beneath the deltoid muscle." *Dorland's* at 1790.

[23] Brachial plexitis is defined as an inflammation of a nerve of the brachial plexus, which is a network of nerves "composed successively of anterior branches and trunks" and "[s]ituated partly in the neck and partly in the axilla." *Dorland's* at 1462.

[24] Brachial plexopathy is "any neuropathy of the brachial plexus." *Dorland's* at 1462.

[25] An electromyogram is "the record obtained by electromyography," which in turn is defined as "an electrodiagnostic technique for recording the extracellular activity . . . of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation." *Dorland's* at 602.

[26] The triceps muscle "extends [the] forearm, [while its] long head adducts and extends [the] arm." *Dorland's* at 1212.

[27] Deep tendon reflexes are "involuntary contraction[s] of a muscle after brief stretching caused by percussion of its tendon." *Dorland's* at 1615.

[28] The biceps brachii muscle "flexes [the] forearm [and] supinates [the] hand." *Dorland's* at 1203.

[29] The pronator teres muscle "flexes [the] elbow and pronates [the] forearm." *Dorland's* at 1209.

[30] The extensor carpi radialis longus is defined as the "long radial extensor muscle of [the] wrist" that "extends and abducts [the] wrist joint." *Dorland's* at 1204.

affect[ed] mainly C7 innervated muscles" and that the findings were most consistent with Parsonage Turner syndrome. *Id.* at 3. He wrote, however, that "the persistent denervation and the localization to mainly C7 muscles at least suggest[ed] the possibility of an ongoing C7 radiculopathy,[31]" while noting that minimal neck and shoulder pain, as well as "fairly clear imaging studies[,] might speak against this[.]" *Id.* Dr. Grant's recommendation was to treat Petitioner's condition as a right C7 radiculopathy because there was "no good treatment for neuralgia amyotrophy[32] [Parsonage Turner syndrome] . . . ." *Id.*

On February 24, 2014, Petitioner had a follow-up visit with Dr. Savino, who noted that the EMG was most consistent with Parsonage Turner syndrome. Pet'r's Ex. 5 at 4. Dr. Savino also noted that despite Dr. Grant's suggestion to treat Petitioner's condition as a cervical radiculopathy, Petitioner felt no pain and his imaging studies had shown no evidence of nerve root impingement that would necessitate such treatment. *Id.* at 6. Therefore, Dr. Savino did not believe that epidural injections for a radiculopathy were warranted, and instead, diagnosed Petitioner with a brachial plexus disorder. *Id.*

On April 9, 2014, Petitioner saw N.P. Millette to discuss treatment for muscle loss to his right side. Pet'r's Ex. 1 at 40. Petitioner reported moderate neck pain and "right shoulder pain with muscle wasting," as well as "weakness in [his] right hand and numbness in [his] right arm." *Id.* He also reported that his condition "started after he had a [f]lu shot" and it was "aggravated by movement." *Id.* Petitioner was referred to a neurologist. *Id.* at 42. Prior to seeing a neurologist, on April 22, 2014, Petitioner saw Dr. Savino for muscle atrophy in his right arm. Pet'r's Ex. 5 at 8. Dr. Savino recommended physical therapy but Petitioner did "not have the [financial] resources to go to physical therapy." *Id.* at 9. Dr. Savino stated that a trial of epidural steroids or a nerve root block were options but thought they would be "low yield and certainly not diagnostic." *Id.* He recommended a neurological assessment. *Id.*

On June 23, 2014, Petitioner saw Dr. Zakir Ali, a neurologist, for his "weakness and atrophy in the right arm." Pet'r's Ex. 4 at 1, ECF No. 5-4. Petitioner reported that immediately after his flu vaccine, "he developed sudden onset pain in the right shoulder region." *Id.* Dr. Ali noted, however, that "[t]his was not in the same area where the injection was given." *Id.* A physical examination revealed 4/5 weakness in the right elbow extension with otherwise normal tone and strength. *Id.* The examination also showed evidence of right arm atrophy, with Petitioner's mid-upper arm circumference measuring 37.5 cm on the right side, compared with 41 cm on the left side. *Id.* There was also "atrophy of the right pectoralis muscle," while DTRs were absent in the right triceps and measured 1/2 for all other upper extremity muscle groups. *Id.* Dr. Ali wrote that Petitioner "had a very typical presentation of [PTS]/neuralgic amyotrophy/idiopathic brachial plexitis a year ago." *Id.* at 2. He also noted the temporal association with the flu vaccine in question and stated that Petitioner's condition "is a very well[]known idiopathic plexitis that can occur with multiple different associations," and that "[v]accinations are common associations." *Id.*

[31] Cervical radiculopathy is a disease of the "cervical nerve roots, often with neck or shoulder pain; compression of nerve roots is a common cause in this area." *Dorland's* at 1571.

[32] Neuralgic amyotrophy is defined as "pain across the shoulder and upper arm, with atrophy and paralysis of the muscles of the shoulder girdle." *Dorland's* at 70.

On April 22, 2015, Petitioner saw N.P. Millette again for "shoulder pain." Pet'r's Ex. 1 at 52. Petitioner reported that he "ha[d] const[ant] neuropathic pain that [was] lasting longer and coming on more frequently" and that "there [was] nothing that t[ook] the pain away." *Id.* Upon physical examination, N.P. Millette noted that Petitioner had "radicular pain . . . extend[ing] from the . . . shoulder, elbow and through the right hand, [with] grip decreased on [the] right." *Id.* at 54. Petitioner was referred to the Oregon Health & Science University's ("OHSU") department of neurology for a consultation regarding his diagnosis of PTS. *Id.*

On September 14, 2015, Petitioner had a follow-up visit with N.P. Millette. *Id.* at 56. Petitioner reported that his neuropathic pain was constant, his "right hand ha[d] gotten worse, his [right] hand f[ell] asleep when he shave[d,] and his index finger f[ell] asleep all the time." *Id.* Upon examination, N.P. Millette noted that Petitioner had "radicular pain . . . extend[ing] from the right shoulder, elbow and through the right hand, [with] grip decreased on [the] right." *Id.* at 58. Petitioner was advised to call or return if his symptoms worsened or persisted. *Id.*

On January 21, 2016, Petitioner had a follow-up with his neurologist, Dr. Ali. Pet'r's Ex. 10 at 1, ECF No. 10. Dr. Ali noted Petitioner "has had not much improvement in the last year from the atrophy and weakness in the right arm . . . [that] started approximately a year and a half ago." *Id.* Dr. Ali indicated that Petitioner's condition had remained unchanged and "ha[d] not worsened." *Id.* He noted Petitioner "continued to have atrophy in the right triceps and the right pectoralis muscles." *Id.* Dr. Ali diagnosed Petitioner with PTS, recommended physical therapy, and prescribed a "[t]rial of [G]abapentin[33] for neuropathic pain in the right arm." *Id.* at 1–2.

On February 12, 2016, Petitioner underwent a physical therapy ("PT") evaluation with Mr. Edsen Donato at Asante Three Rivers Medical Center ("Asante"). Pet'r's Ex. 11 at 1, ECF No. 13. Petitioner complained of "[r]ight shoulder pain and weakness with muscle atrophy, left shoulder pain [and] numbness of the left dorsal thumb and index finger." *Id.* Petitioner reported that "due to his condition, he compensated by using his left shoulder more and that, as a result, he began to have left shoulder pain as well." *Id.* The physical therapist noted "no significant tenderness . . . in the right shoulder, but . . . significant atrophy . . . in the right triceps and pectoralis musculature." *Id.* at 2. He also noted that the ROM of Petitioner's right shoulder was "grossly [eighty percent] of normal due to pain limitations[,] while his strength was "grossly 4/5." *Id.* Mr. Donato's impression was "[m]uscle power deficit/deconditioning syndrome of bilateral shoulders[]" and "[p]robable left shoulder impingement syndrome due to overuse." *Id.* at 3. He recommended PT two times per week for four-to-six weeks. *Id.*

Petitioner had a total of eight PT sessions at Asante from February 12, 2016 to July 1, 2016. Pet'r's Ex. 13 at 3, ECF No. 20. Petitioner made a PT re-certification request on July 1, 2016. *Id.* In the PT re-certification and plan of care report, Mr. Donato noted that Petitioner had "[p]ersistent right shoulder pain (6/10) with radiation to his right arm with numbness in his right dorsal hand." *Id.* Petitioner described his pain as "dull [and] achy." *Id.* at 4. Petitioner also reported that "his left shoulder ha[d] improved by about [ten percent] since beginning therapy." *Id.* at 3. Petitioner stated that his condition, particularly in the left side, was aggravated when "[r]eaching overhead, lifting, [or] carrying objects." *Id.* at 4. A physical examination revealed "no redness, bruising or swelling

[33] Gabapentin is "an anticonvulsant that is a structural analogue of γ-aminobutyric acid (GABA), used as adjunctive therapy in the treatment of partial seizures." *Dorland's* at 753.

noted in the shoulders . . . no significant tenderness . . . in the right shoulder, but . . . significant atrophy . . . in the right triceps and pectoralis musculature." *Id.*

In July and August 2016, Petitioner underwent six additional PT sessions. *See id.* at 6–11; Pet'r's Ex. 18, ECF No. 26-2. Petitioner continued to complain of "persistent mild to moderate pain and weakness in his left shoulder especially with overhead activities, and a persistent pain in his right[-]side neck/shoulder region that radiate[d] down to his right hand." *See* Pet'r's Ex. 18 at 2. He also reported that "the pain in his right shoulder [was] more bothersome to him than his left shoulder." *Id.* At his last PT session on August 3, 2016, Petitioner reported that he was "[f]eeling like it [was] not getting any better[;] left side maybe slightly." *Id.* at 1.

B. Petitioner's Affidavits

Petitioner submitted three separate affidavits in support of his claim. Petitioner executed his first affidavit on December 20, 2015, but it was not filed until June 11, 2019. Pet'r's Ex. 89, ECF No. 69. In this affidavit, Petitioner adopted all the statements made in his petition as true under penalty of law. *Id.* at 1–2. Petitioner also noted that, although "fairly accurate,"[34] the medical records "do not reflect all discussions had by and between [his] treating physicians or every detail of those discussions." *Id.* at 1. He also noted that the records sometimes erroneously document that his pain occurred on his left side rather than on his right. *Id.* at 1–2.

In the petition, Petitioner stated that "prior to his vaccine injury, [he] enjoyed early morning gym workouts which included bench pressing [three hundred and fifteen] pounds[.]" Pet. at 1. Petitioner elaborated that "[o]n the weekends, he enjoyed hiking, biking, boating, snowboarding, [and] waterboarding[.]" *Id.* He also wrote that "[h]e owns his own landscaping business," and that his work involves "[s]ignificant heavy lifting[,]" with long ten to twelve-hour workdays, five to six days a week. *Id.* Petitioner explained that his previous sports injury "would cause moderate pain in his lower back and later on his left side[]" when it became irritated. *Id.* at 2. He also noted that prior to his vaccination, he was "successfully" treating this injury "with the use of methadone and chiropractic care." *Id.*

Petitioner stated that he "continues to suffer" from his PTS and does not receive much treatment for it. *Id.* at 3. He explained that he "has not sought out much more treatment as he can ill afford numerous doctor visits" and because Dr. Ali informed him that "there really was no treatment[.]" *Id.* He noted that "the pain on his right comes and goes[]" and that "[t]he intermittent pain, numbness[,] and tingling in his hands and pain in his arm and shoulder cause[] issues with daily activities such [as] shaving, brushing his hair[,] and brushing his teeth." *Id.* at 4. Petitioner also reported that his "extreme fatigue and weakness remain[]" and that he can no longer "weight train as he used to and also go to work." *Id.* Petitioner stated that he has been unable "to take part in his weekend recreational activities[]" because of his PTS. *Id.* He also noted that "[d]riving has become difficult[,]" and that on a trip to San Jose, CA, on April 22, 2015, "the pain was so severe[,] he had to stop and wasn't sure he would be able to drive home." *Id.* at 3–4.

[34] Petitioner noted that the records filed in support of his claim sometimes erroneously document that his pain occurred on his left side rather than on his right side. *See* Pet'r's Ex. 89 at 1–2.

Petitioner also explained that PTS has affected his professional life as well. He indicated that he "had to hire an employee to help with what he can no longer complete in a day due to his fatigue and exhaustion[,]" and he now "has to go home in the middle of the workday to take a nap." *Id.* at 4. He also stated that "his arm especially bothers him when he is installing irrigation control clocks, digging, raking, lifting, working overhead and trying to lift heavy items." *Id.*

Petitioner submitted a supplemental affidavit on December 14, 2017, in the form of a declarative response to Dr. Leist's expert report. Pet'r's Ex. 84, ECF No. 53-1. Petitioner wrote that his sports injury prior to the vaccination in question was "related to [his] *left* side, which is clearly indicated in [his] medical records." *Id.* at 1 (emphasis in original). He also noted that he "developed an immediate pain in [his] *right* shoulder region[]" after receiving the flu vaccine, which "was very different from [his] left shoulder [pain]." *Id.* at 1–2 (emphasis in original).

Petitioner explained that although he did not report the right shoulder pain to a doctor immediately after the vaccination, he did so when the "pain to [his] right shoulder blade area commenced on or about February 7, 2013, approximately 24 days after the vaccination[.]" *Id.* at 2. He indicated that soon after, he called "Thorson chiropractic on February 12, 2013, when the pain did not go away." *Id.* Petitioner also noted that because he had not injured his right shoulder prior to the vaccination in question, his chiropractor's notes "clearly indicate[] a new injury on [his] *right* side." *Id.* (emphasis in original). In response to Dr. Leist's statement that Petitioner's medical records do not indicate his "weakness" until approximately five months after receiving the vaccine, Petitioner wrote that Dr. Grant's notes from February 4, 2014, indicating that Petitioner's atrophy and weakness lasted "six to nine months[,]" are "consistent with [his] recollection of events regarding [his] weakness and the commencement of muscle mass loss." *Id.* at 2–3.

Petitioner also expressed that, contrary to Dr. Leist's claim, his divorce in the spring of 2013 was not "a psychological stressor [that] may have been a cause of [his] brachial neuritis." *Id.* at 3. In fact, Petitioner explained, his "divorce was a very simple, uncontested, and reasonably amicable dissolution." *Id.* Petitioner argued that this is supported by the fact that his "former wife and [he] lived together during the divorce . . . until [she] could find an appropriate residence." *Id.* Petitioner also noted that he "assisted with [his former wife's] move" and "did not consider this mutual dissolution a stressful situation." *Id.*

In response to my July 9, 2019 scheduling order, Petitioner submitted his second supplemental affidavit on August 8, 2019. *See* Pet'r's Ex. 95. Petitioner wrote that, "from [his] interpretation of the Order, [he] ha[d] been asked to provide an explanation for discrepancies within the medical records regarding the severity of the pain experienced and the onset time." *Id.* at 2. He explained, "[a]s a rule, [he] ha[s] a pretty high tolerance for pain; and, [he is] not one to complain, in general." *Id.* Petitioner further expressed that if he had known he would later require use of the Program, "[he] would not have been so careless with reporting when the pain actually started[,] or its severity." *Id.*

Petitioner explained that what he did know regarding the time of onset was that "it cause[d him] to call [his] chiropractor on February 12, 2013 and that the pain had been around for a week before that." *Id.* Petitioner also wrote that he "find[s] it difficult to quantify the intensity of pain

when given a scale of 1 to 10." *Id.* For example, Petitioner asked, "[w]hat is a 10?" *Id.* Nonetheless, Petitioner noted that he reported his pain "was constant, dull, burning[,] and getting worse." *Id.*; *see also* Pet'r's Ex. 2 at 3. Yet, Petitioner highlighted that "every doctor described [his] pain differently." Pet'r's Ex. 95 at 3. Petitioner noted that the doctor who described his pain as starting "rather insidiously[,]" applied his own terminology since "[t]he word 'insidiously' is not a term [he] ha[s] ever used." *Id.* However, Petitioner clarified that the pain in his neck and shoulder "was suddenly there and with great intensity about a week before [he] saw [his] chiropractor on February 14, 2013." *Id.*

III. Expert Reports

A. Petitioner's Expert, M. Eric Gershwin, M.D., M.A.C.P., M.A.C.R.

Dr. Gershwin received his medical degree from Stanford University in 1971. Pet'r's Ex. 24 at 1, ECF No. 41-2. He is licensed to practice in several states, including California, and holds board-certifications in internal medicine, internal medicine with a subspecialty in rheumatology, and allergy and clinical immunology. *Id.* at 2. He also holds a Master of Science in Astronomy and Astrophysics from the Centre for Astrophysics and Supercomputing in Melbourne, Australia. *Id.* Dr. Gershwin has an honorary doctorate, or "Honoris Causa," from the University of Athens, Greece, in recognition of his lifetime contributions in immunology and medicine. *Id.* Dr. Gershwin has also been awarded the AESKU Prize in Autoimmunity for his lifetime contribution in immunology, and the Vasco Da Gama Prize for "a lifetime of deep explorations in immunology to benefit mankind." *Id.*

Dr. Gershwin's post-doctoral training includes a two-year residency at the Tufts-New England Medical Center in Boston, Massachusetts, two years as a clinical associate in immunology at the National Institutes of Health in Bethesda, Maryland, and two years as an Assistant Professor of Medicine in Rheumatology and Allergy at the University of California School of Medicine in Davis, California ("UC Davis"). *Id.* at 2. Dr. Gershwin then went on to become the Director of the Special Immunology Diagnostic Laboratory at UC Davis. *Id.* He has been a Professor of Medicine, specializing in Rheumatology and Allergy, at UC Davis since 1981 and a Chief of the Division of Rheumatology/Allergy and Clinical Immunology since 1982. *Id.* at 1.

Dr. Gershwin is also a fellow with the American Academy of Allergy and Immunology, the American College of Physicians, and the American College of Rheumatology. *Id.* at 3–4. He currently serves as the editor-in-chief for the Journal of Autoimmunity and Clinical Reviews in Allergy, as co-editor-in-chief for Autoimmunity Reviews, and as co-editor for Reviews in Autoimmunity. *Id.* at 5. Dr. Gershwin's curriculum vitae lists numerous books, book chapters, and research papers of which he is a listed author. *See id.* at 8–125.

Dr. Gershwin submitted one expert report and four supplemental reports in this case. *See* Pet'r's Ex. 23, ECF No. 41-1; Pet'r's Ex. 80, ECF No. 51-1; Pet'r's Ex. 85, ECF No. 58-1; Pet'r's Ex. 90, ECF No. 72-1; Pet'r's Ex. 96, ECF No. 77-1.

1. Dr. Gershwin's Expert Report

Dr. Gershwin submitted his expert report on June 8, 2017. Pet'r's Ex. 23. Dr. Gershwin opined that Petitioner's PTS, "or right-sided brachial plexus neuritis[,] . . . occurred because of the inflammatory response secondary to the influenza vaccine that he received on January 14, 2013." *Id.* at 5. He noted that "the inflammatory response and, in particular, the homing and traffic following inflammatory stimulation[,] . . . led to this injury." *Id.*

Dr. Gershwin wrote that PTS is a "rare disorder," affecting "1.64 cases per [one hundred thousand]"[35] people annually, that is "typically characterized by an abrupt onset of upper extremity pain followed by progressive neurologic deficits, including weakness, atrophy, and occasionally sensory abnormalities."[36] *Id.* at 2. He also noted that the acute form of brachial neuritis "is characterized by a rapid or acute onset of pain, accompanied by profound weakness." *Id.* Dr. Gershwin explained that although the etiology of PTS is "unknown[,] . . . the inciting event may be trauma, extreme exercise, surgery, childbirth, bacterial, viral or parasitic infections, immunization[,] or botulinum toxin A injection."[37] *Id.* He did note, however, that "in most cases there is no obvious precipitating event." *Id.* Dr. Gershwin further explained that "[t]he diagnosis is made on the basis of the medical history, the presence of decreased muscle strength and atrophy, the electrophysiologic findings[,] and the exclusion of other possible causes . . . ."[38] *Id.* Dr. Gershwin cited a case study by Devathasan et al. of twenty-one patients with neuralgic amyotrophy to note that the five criteria proposed for diagnosing PTS are, "weakness of the shoulder muscles, exclusion of other possible causes of the shoulder problem, pain in the affected region, electromyographic findings, and spontaneous recovery, whether complete or incomplete."[39] *Id.* The authors of the study concluded that "[w]hile the first two [criteria] are taken as absolute criteria, the remaining three are very characteristic but may not be present when the patient is first seen." *See* Pet'r's Ex. 47 at 1, ECF No. 43-5.

---

[35] Citing Pet'r's Ex. 44, ECF No. 43-2, Beghi E., et al., *Brachial Plexus Neuropathy in the Population of Rochester, Minnesota, 1970–1981*, ANN. NEUROL. 1985; 18:320–23.

[36] Citing Pet'r's Ex. 25, ECF No. 41-3, Smith C.C., & Bevelaqua A.C., *Challenging Pain Syndromes: Parsonage-Turner Syndrome*, PHYS. MED. REHABIL. CLIN. N. AM. 2014; 25:265–77.

[37] Citing Pet'r's Ex. 37, ECF No. 42-5, Vanermen B., et al., *The Syndrome of Parsonage and Turner. Discussion of Clinical Features with a Review of 8 Cases*, ACTA. ORTHO. BELG. 1991; 57:414–19; Pet'r's Ex. 40, ECF No. 42-8, Malamut R.I., et al., *Postsurgical Idiopathic Brachial Neuritis*, MUSCLE NERVE 1994; 17:320–24; Pet'r's Ex. 41, ECF No. 42-9, Lederman R.J. & Wilbourn A.J., *Postpartum Neuralgic Amyotrophy*, NEUROL. 1996; 47:1213–19; Pet'r's Ex. 42, ECF No. 42-10, Hamati-Haddad A. & Fenichel G.M., *Brachial Neuritis Following Routine Childhood Immunization for Diphtheria, Tetanus, and Pertussis (DTP): Report of Two Cases and Review of the Literature*, PEDIATRICS 1997; 99:602–03; Pet'r's Ex. 43, ECF No. 43-1, Sheean G.L., et al., *Pain and Remote Weakness in Limbs Injected with Botulinum Toxin A for Writer's Cramp*, LANCET 1995; 346:154–56.

[38] Citing Pet'r's Ex. 45, ECF No. 43-3, Flaggman P.D. & Kelly J.J., Jr., *Brachial Plexus Neuropathy. An Electrophysiologic Evaluation*, ARCH. NEUROL. 1980; 37:160–64; Pet'r's Ex. 46, ECF No. 43-4, Subramony S.H., *AAEE Case Report #14: Neuralgic Amyotrophy (Acute Brachial Neuropathy)*, MUSCLE NERVE 1988; 11:39–44.

[39] Citing Pet'r's Ex. 47, ECF No. 43-5, Devathasan G. & Tong H.I., *Neuralgic Amyotrophy: Criteria for Diagnosis and a Clinical with Electromyographic Study of 21 Cases*, AUST. N. Z. J. MED. 1980; 10:188–91.

Dr. Gershwin opined that, based on Petitioner's medical records and the above facts regarding PTS, Petitioner's PTS is not the result of a trauma but instead "is secondary to the inflammatory response to the vaccination" in question. Pet'r's Ex. 23 at 3. Dr. Gershwin explained that "[t]he vaccination produced a significant cytokine response that facilitated recruiting and homing of lymphocytes." *Id.* He wrote that this "[r]ecruitment of white cells or leukocytes is a critical response to virtually everything from infection to non-specific tissue injury and in fact interplays with diseases as diverse as rheumatoid arthritis,[40] atherosclerosis[41][,] and virtually every other autoimmune disease."[42] *Id.* Dr. Gershwin relied on the literature to explain that "flowing leucocytes roll along the endothelium,[43] in a manner dependent on the binding of selectins[44] to their ligands."[45, 46] *Id.* "The rolling-dependent slowing down of leucocytes," he continued, "promotes the exposure of leucocytes to chemokines deposited on the endothelial cell surface."[47] *Id.* Chemokines then "induce the activation of leucocyte and their integrins, thereby promoting high-affinity integrin-dependent firm leucocyte arrest." *Id.* Dr. Gershwin also explained that "[s]electin-mediated and integrin-dependent adhesive events synergize in the process of slow rolling, which follows fast rolling and precedes firm [leucocyte] arrest[.]"[48] *Id.* Dr. Gershwin

---

[40] Rheumatoid arthritis is defined as "a chronic systemic disease primarily of the joints, usually polyarticular, marked by inflammatory changes in the synovial membranes and articular structures and by muscle atrophy and rarefaction of the bones. In late stages, deformity and ankylosis develop. The cause is unknown, but autoimmune mechanisms and virus infection have been postulated." *Dorland's* at 157.

[41] Atherosclerosis is "a common form of arteriosclerosis with formation of deposits of yellowish plaques (atheromas) containing cholesterol, lipoid material, and lipophages in the intima and inner media of large and medium-sized arteries." *Dorland's* at 172. Arteriosclerosis is "characterized by thickening and loss of elasticity of arterial walls." *Id.* at 144.

[42] Citing Pet'r's Ex. 57, ECF No. 44-5, Chavakis T., *Leucocyte Recruitment in Inflammation and Novel Endogenous Negative Regulators Thereof*, EUR. J. CLIN. INVEST. 2012; 42:686–91.

[43] The endothelium is "the layer of epithelial cells that lines the interior of structures such as the cavities of the heart, the lumina of blood and lymph vessels, and the serous cavities of the body; it originates from the mesoderm." *Dorland's* at 621.

[44] The function of selectins is to "mediate the binding of leukocytes to the vascular endothelium." *Dorland's* at 1689.

[45] A ligand is "a molecule that binds to another molecule, used especially to refer to a small molecule that binds specifically to a larger molecule, e.g., an antigen binding to an antibody, a hormone or neurotransmitter binding to a receptor, or a substrate or allosteric effector binding to an enzyme . . . ." *Dorland's* at 1051.

[46] *See* Chavakis, *supra* note 42, at 686–91.

[47] Citing Pet'r's Ex. 59, ECF No. 44-7, Chavakis E., et al., *Novel Aspects in the Regulation of the Leukocyte Adhesion Cascade*, THROMB. HAEMOST. 2009; 102:191–97; Pet'r's Ex. 64, ECF No. 45-2, Hyduk S.J., et al., *Phospholipase C, Calcium, and Calmodulin Are Critical for Alpha4betal Integrin Affinity Up-regulation and Monocyte Arrest Triggered by Chemoattractants*, BLOOD 2007; 109:176–84; Pet'r's Ex. 65, ECF No. 45-3, Kinashi T., *Intracellular Signalling Controlling Integrin Activation in Lymphocytes*, NAT. REV. IMMUNOL. 2005; 5:546–59; Pet'r's Ex. 66, ECF No. 45-4, Lafuente E. & Boussiotis V.A., *Rap1 Regulation of RIAM and Cell Adhesion*, METHODS ENZYMOL. 2006; 407:345–58; Pet'r's Ex. 67, ECF No. 45-5, Shamri R., et al., *Lymphocyte Arrest Requires Instantaneous Induction of an Extended LFA-1 Conformation Mediated by Endothelium-bound Chemokines*, NAT. IMMUNOL. 2005; 6:497–506.

[48] Citing Pet'r's Ex. 73, ECF No. 43-1, Zarbock A., et al., *Spleen Tyrosine Kinase Syk is Necessary for E-selectin-induced Alpha(L)beta(2) Integrin-mediated Rolling on Intercellular Adhesion Molecule-1*, IMMUNITY 2007; 26:773–83; Pet'r's Ex. 75, ECF No. 46-3, Salas A., et al., *Rolling Adhesion Through an Extended Conformation of Integrin AlphaLbeta2 and Relation to Alpha I and Beta I-like Domain*

stressed the immune response's dependence "on the 'co-ordination of lymphocyte migration.'"[49] *Id.* He explained that the "orchestration of immune cell movement is provided by specific homing signals that leucocytes receive via chemokines and chemokine receptors." *Id.* at 3–4. He also noted that chemokines "are key factors in lymphocyte trafficking[]" and their "biology is exerted through chemokine receptors," which "are particularly amenable to pharmacological blockade with small molecule inhibitors or receptor antagonists." *Id.* at 4.

Regarding the timing of onset of Petitioner's PTS symptoms, Dr. Gershwin stated that they "are consistent with what we would expect." *Id.* Specifically, Dr. Gershwin wrote that "the new onset of severe discomfort in [Petitioner's] right shoulder" occurred approximately three weeks post-vaccination, i.e., on February 7, 2013. *Id.* He then used the example of tetanus toxoid-type vaccinations to gauge onset, arguing that "the vaccine injury table acknowledges that the onset of brachial neuritis could be anywhere between [two to twenty-eight] days." *Id.* He also argued that "the original report by Parsonage and Turner from Lancet in 1948 specifically points [vaccination] out as a precipitating factor[,]" with eleven out of sixty-seven vaccinees developing shoulder-girdle symptoms four weeks post-vaccination and six within two weeks.[50] *Id.* However, the original report by Parsonage and Turner discusses one specific case of a man "given intravenous T.A.B.[51]. . ." rather than the influenza vaccine. *See* Pet'r's Ex. 31 at 2. The authors continued, "[t]wo hours later he developed severe pain across the back of both shoulders, . . ." and the next day "he developed a complete paralysis of the left serratus magnus.[52]" *Id.* Dr. Gershwin emphasized:

> the initial (can be microscopic) onset of inflammation would occur within days but the expansion that will produce the requisite magnitude of inflammation to become clinically significant will vary between individuals, . . . and can take much longer for a clinical response to be perceived as neuropathic to the patient; [six] weeks would be the outside limits.

Pet'r's Ex. 23 at 4. He argued that although tetanus vaccinations are most commonly cited because, like the flu vaccine, they are "often given multiple times to patients over a lifetime and therefore more likely to elicit an immediate and more intense response[] . . . any vaccine including influenza can have the same potential, dictated by previous exposure and/or the nature and intensity of an individual response to a vaccination." *Id.* Overall, Dr. Gershwin concluded that, more likely than not, Petitioner's flu vaccination led to his PTS.

Interaction, IMMUNITY 2004; 20:393–406.

[49] Citing Pet'r's Ex. 76, ECF No. 46-4, Comerford I., et al., *Advances in Understanding the Pathogenesis of Autoimmune Disorders: Focus on Chemokines and Lymphocyte Trafficking*, BR. J. HAEMATOL. 2014; 164:329–41.

[50] Citing Pet'r's Ex. 31, ECF No. 41-9, Parsonage M.J. & Turner J.W., *Neuralgic Amyotrophy; the Shoulder-girdle Syndrome*, LANCET 1948; 1:973–78.

[51] This vaccine is used to fight against typhoid fever. Pet'r's Ex. 31 at 1–2.

[52] The serratus magnus is one of the serratus muscles of the shoulder and thorax. *Dorland's* at 1201.

2. Dr. Gershwin's First Supplemental Expert Report

In response to Dr. Leist's responsive expert report, Dr. Gershwin submitted his first supplemental expert report on November 21, 2017. Pet'r's Ex. 80. In his report, Dr. Gershwin first addressed certain "factual errors" Dr. Leist made in his report. *Id.* at 1. Dr. Gershwin noted, as an example, that in "a number of notations[,]" Dr. Leist failed to make the distinction that Petitioner's pre-vaccine sports injury was "on [Petitioner's] lower back and his '*left'* side." *Id.* (emphasis in original). Dr. Gershwin opined that "one could interpret this lack of clarity as an indication that [Petitioner] had a pre-existing injury[; h]e did have a pre-existing injury but it was to his left side." *Id.* He then clarified that Petitioner's "post[-]vaccine injury was to his *right* side." *Id.* (emphasis in original).

Next, Dr. Gershwin highlighted the differences with respect to his and Dr. Leist's interpretation of the mechanisms which led to Petitioner's PTS. *See id.* First, Dr. Gershwin stated that he was "surprised" that Dr. Leist analogized PTS and Guillain-Barré syndrome ("GBS") to explain that the time interval for the onset of symptoms is similar in both illnesses. *Id.* Dr. Gershwin indicated that "there are no immunological similarities between Guillain-Barr[é] and Parsonage Turner." *Id.* He continued that "the latency time between the onset of autoimmune diseases and the first appearance of autoantibodies can range from days to years." *Id.* But he argued that even if the timing of onset between the two diseases was the same, Petitioner's phone call to his chiropractor on February 12, 2013, and subsequent visit two days later show that the onset of his symptoms "commenced around February 5, 2013[,] directly down the strike zone of Dr. Leist's opinion as to when one would see first onset symptoms in a GBS case." *Id.* at 1–2. Dr. Gershwin expressed his opinion that he "do[es] not interpret the records to indicate that [Petitioner's] onset symptoms occurred five-(5) month[s] after administration of the influenza vaccine." *Id.* at 2.

Further, Dr. Gershwin noted that Dr. Leist cited a case report by Weintraub and Chia[53] to argue that muscle atrophy occurs within two weeks post-vaccination in PTS cases and not five months later as reported in Petitioner's case. *Id.* However, Dr. Gershwin argued that "the spectrum of how Parsonage Turner can evolve is vast and does not turn on just one case report." *Id.* He also argued that Petitioner's reporting of right pectoral muscle atrophy on July 8, 2013, does not necessarily mean that that was the onset of his weakness but simply the date on which it "was reported and *recorded* in a medical record." *Id.* (emphasis in original).

Additionally, Dr. Gershwin opined that Petitioner's weakness is not the most important symptom because "it is not the heralding event" of PTS. *Id.* Rather, he explained, the Vaccine Injury Table's "Qualifications and Aid to Interpretation [for PTS] "states, among other things[,] that 'a deep, steady, often severe aching *pain* in the shoulder and upper arm usually heralds onset of the condition.'"[54] *Id.* (emphasis in original). Dr. Gershwin opined "that's exactly what we have here in [Petitioner's] case[,]" and argued that although "the medical records are unclear as to when the weakness commenced[,]" they clearly show when Petitioner's pain commenced, as the "quality of his workouts changed significantly" at that time. *Id.* Dr. Gershwin also wrote that "most vaccine injuries are, by definition, atypical[,]" with "approximately [fifteen percent] of [PTS] cases

[53] Citing Resp't's Ex. A-2, ECF No. 49-3, Weintraub M.I. & Chia D.T.S., *Paralytic Brachial Neuritis After Swine Flu Vaccination*, ARCH. NEUROL. 1977; 34:518.
[54] *See* 42 U.S.C.A. § 300aa-14(c)(6).

occur[ring] after immunization."[55] *Id.* He also noted that PTS "is typically characterized by an abrupt onset of upper extremity pain followed by progressive neurologic deficits, including weakness, atrophy and occasionally sensory abnormalities[,]" as seen in Petitioner's case. *Id.* Dr. Gershwin also cited the van Alfen and van Engelen study,[56] which included two-hundred and forty-six PTS patients, to show that pain was the most important onset symptom, with weakness appearing "in 27.2 [percent] of all cases . . . [more] than two weeks later." *Id.*

Dr. Gershwin noted that Dr. Leist used the van Alfen and van Engelen study to specify four events as a cause for PTS: "infection, exercise, surgery[,] and peripartal." *Id.* at 3. However, Dr. Gershwin argued that the study authors themselves "indicated that the broad range of symptoms encountered in their study could be influenced by the fact that about a third of the patients were especially referred to their center because of a somehow atypical clinical picture, according to their referring physician." *Id.* He also wrote that the letter to the editor[57] cited by Dr. Leist "acknowledges that Parsonage Turner may occur after inoculations[,]" and that "'[t]he cause of paralytic brachial neuritis usually is considered to be a post[-]infectious reaction or a reaction secondary to an allergic or hypersensitivity response.'" *Id.* Additionally, Dr. Gershwin explained that, unlike Dr. Leist's claims to the contrary, Petitioner's divorce could not have led to his PTS because his "divorce was reasonably amicable and [was] an undisputed divorce done by a paralegal." *Id.* Regarding Dr. Leist's claim that Petitioner's exercise regimen could have caused his PTS, Dr. Gershwin opined that that would "be unlikely as [Petitioner] had been in sports . . . quite some time without brachial neuritis, but, developed Parsonage Turner/brachial neuritis right after the flu vaccine." *Id.* Therefore, his opinion remained unchanged that "more likely than not[,] it was the flu vaccine that caused Parsonage Turner, or at [a] minimum, was the substantial factor in causing it." *Id.*

Lastly, Dr. Gershwin reiterated that "vaccination promotes inflammation in the draining lymph node, something which is directly relevant to [Petitioner]." *Id.* Specifically, Dr. Gershwin opined that "genetic predisposition is critical to understanding the rare events that can occur in individuals following vaccination[,]" implying that genetic predisposition could have played a role in the instant case. *Id.* He also explained that "[t]he mechanism by which inflammation influences the adaptive response to vaccines is not fully understood." *Id.* Nevertheless, he continued, lymph node macrophages ("LNMs") play an important role "in the induction of the cytokine storm triggered by inactivated influenza virus vaccine." *Id.* He explained that "LNMs undergo inflammasome-independent necrosis-like death [post vaccination, which] . . . releases prestored interleukin-lα (IL-lα)." *Id.* "[A]ctivated medullary macrophages [also] produce interferon-β (IFN-β) that induces the autocrine secretion of IL-1α." *Id.* He continued, "macrophage depletion promotes lymph node-resident dendritic cell ("LNDC") relocation and affects the capacity of CDl lb+ LNDCs to capture virus and express co-stimulatory molecules." *Id.* Thus, "[i]nhibition of the IL-lα-induced inflammatory cascade reduce[s] B cell responses, while co-administration of recombinant IL-1α increase[s] the humoral response." *Id.*

---

[55] *See* Smith & Bevalaqua, *supra* note 36, at 265–77.
[56] *See* Pet'r's Ex. 26, ECF No. 41-4, van Alfen N. & van Engelen B.G., *The Clinical Spectrum of Neuralgic Amyotrophy in 246 Cases,* BRAIN 2006; 129:438–50.
[57] *See* Weintraub & Chia, *supra* note 53, at 518.

3. Dr. Gershwin's Second Supplemental Expert Report

Dr. Gershwin submitted his second supplemental expert report on March 20, 2018, in response to Dr. Leist's first supplemental report. Pet'r's Ex. 85. In his report, Dr. Gershwin explained "the mechanism of [Petitioner's] injury relates entirely to the milestones and chain of events that occurred following his vaccination." *Id.* at 1. He then addressed "critical notations within the records" which he believes Dr. Leist "missed . . . that make his interpretation of the chronology incorrect." *Id.*

Dr. Gershwin expressed that it is important to understand the progression of PTS in order to appreciate the onset of PTS symptoms in Petitioner. *Id.* Dr. Gershwin explained that the symptoms of PTS "can vary from acute to insidious[,]" with "[a]cute onset [being] characterized by pain in the shoulder or upper arm, while insidious onset can manifest as progressive pain, evolving numbness, weakness of selected muscles, or any combination."[58] *Id.* In the early stages of the disease, he continued, "distinguishing between symptoms arising from bones and ligaments about the shoulder and those from nerves in the plexus may be difficult." *Id.* He also wrote, "[a]cute onset, in the absence of trauma, favors a metabolic or inflammatory process[,]" while clinical signs "include muscle weakness, atrophy, and sensory loss." *Id.* Additionally, because "it may be difficult to distinguish true weakness from reduced effort due to pain[,] . . . [m]uscle atrophy may not be appreciated for several weeks." *Id.*

Dr. Gershwin continued his criticisms of Dr. Leist and noted that Dr. Leist characterized the onset of Petitioner's PTS by the sensation of weakness five months post-vaccination, thereby "ignor[ing an] . . . earlier notation of pain within the records." *Id.* at 2. Thus, he argued, Dr. Leist erroneously "concludes that the onset is too late for a vaccine association." *Id.* By contrast, he argued, based on Petitioner's medical records, "the onset would be approximately February 4, 2013, with weakness occurring a week or two after the visit to the chiropractor." *Id.* Dr. Gershwin also pointed out "that this chronology of [Petitioner's] symptoms is very consistent with the description" he provided of PTS. *Id.*

Dr. Gershwin also wrote that "[he] cannot understand why Dr. Leist believes that the influenza vaccine was not administered in the right deltoid muscle." *Id.* He continued that Dr. Leist misinterpreted Dr. Ali's notes in his assessment of Petitioner's injury during his June 23, 2014 visit. *Id.* Specifically, Dr. Gershwin argued that Dr. Leist "t[ook] one sentence from a medical record note out of context when compared to the totality of the records." *Id.* He argued that Dr. Leist failed to interpret the notation "from the patient perspective, who . . . differentiates between his *shoulder blade region* from his right *deltoid muscle*, the deltoid, being . . . the site where most arm vaccines are administered." *Id.* (emphasis added). He also noted that Petitioner's earlier chiropractor records state that Petitioner "'developed severe pain in his right *shoulder blade area*.'"[59] *Id.* (emphasis in original). Dr. Gershwin therefore argued that the record in its totality shows that "the vaccine was given in the right deltoid muscle, which is not the same area as where the pain commenced[]"– the right shoulder blade area. *Id.*

---

[58] Dr. Gershwin relies on an excerpt from the UpToDate website regarding brachial plexus syndrome, available at https://www.UpToDate.com/contents/brachial-plexus-syndromes/print.

[59] Citing Pet'r's Ex. 2 at 4–5.

Dr. Gershwin stated that Dr. Leist's disagreement with the lymph node drainage mechanism proposed by Dr. Gershwin is "a misinterpretation." *Id.* He explained that "virtually every physician is aware of the local swelling of lymph nodes which can occur following a vaccination[,]" and that "injections in *either* arm can produce bilateral swelling." *Id.* (emphasis in original). He therefore argued that "it does not matter which arm received the injection[]" in Petitioner's case. *Id.* In fact, he continued, "the Vaccine Injury Table – Qualifications and Aids to Interpretation for Brachial Neuritis (c)(6) acknowledges this point[,]" explaining that "'[t]he neuritis, or plexopathy, may be present on the same side or on the side opposite the injection. It is sometimes bilateral, affecting both upper extremities . . . .'"[60] *Id.*

Dr. Gershwin concluded by arguing that Dr. Leist was incorrect in asserting that "'the onset of weakness reported by [Petitioner] on July 8, 2013[,] to have arisen two months earlier . . . is outside the time window . . . for an immune complication following non-live influenza vaccine.'"[61] *Id.* at 3. He argued that Dr. Leist misinterpreted the relevant medical record, which states that Petitioner reported that he had been "'very weak and ha[d] lost a lot of strength on his right[-]side x 2 months.'"[62] *Id.* A closer reading of the notation, Dr. Gershwin argued, shows that Petitioner did not report that his weakness had occurred two months before July 8, 2013. *Id.* Overall, Dr. Gershwin opined that Dr. Leist had not read or interpreted the medical records correctly. *Id.*

4. Dr. Gershwin's Third Supplemental Expert Report

Dr. Gershwin submitted his third supplemental expert report on August 8, 2019, in response to my order requesting a more concise report regarding the causation theory as it applies to Petitioner's PTS. Pet'r's Ex. 90 at 1. In support of his arguments in this report, Dr. Gershwin submitted literature generally describing the mechanics of lymph circulation.[63] *Id.* at 2. Based on this, Dr. Gershwin maintained that Petitioner developed PTS due to the flu vaccine. *Id.* He relied on the fact that "[Petitioner's] right upper extremity had no significant pathology prior to vaccination[] . . . [and t]here are no other physical insults that [he] ha[s] found within the medical records . . . that can explain the development of PTS." *Id.* at 1–2.

Dr. Gershwin further explained that, "[f]ollowing [a] vaccination, one would expect the development and recruitment of regional lymph nodes . . . [which] may lead to localized pain at the injection site." *Id.* at 1. This recruitment of such lymphocytes and the successful development of vaccine antibodies requires the immune system to process the vaccine. *Id.* Doing so "lead[s] to lymphocyte activation, particularly in regional lymph nodes." *Id.* Dr. Gershwin applied the concept of lymphocyte activation to Petitioner's PTS and opined that Petitioner's "pain in his right shoulder blade area approximately three weeks following the vaccination[,] . . . would be consistent with irritation and pressure from expanding regional lymph nodes secondary to the vaccine." *Id.* Dr.

[60] *See* 42 U.S.C.A. § 300aa-14(c)(6).
[61] Citing Resp't's Ex. C at 4.
[62] Citing Pet'r's Ex. 1 at 30.
[63] Pet'r's Ex. 92, ECF No. 72-3, Reddy N.P., *Lymph circulation: physiology, pharmacology, and biomechanics,* CRIT. REV. BIOMED. ENG. v. 14(n. 1), 1986, p. 45–91; Pet'r's Ex. 93, ECF No. 72-4, Moore J.E., et al., *Lymphatic System Flows,* ANN. REV. FLUID MECH. 2018; 50:459–82; Pet'r's Ex. 94, ECF No. 72-5, Macdonald A.J., et al., *Modeling flow in collecting lymphatic vessels: one-dimensional flow through a series of contractile elements,* AM. J. PHYSIOL. HEART CIRC. PHYSIOL. 2008; 295:H305–313.

Gershwin asserted that had a physical or CT scan been performed by Petitioner's chiropractor during his February 14, 2013, examination, it would have been "consistent with an inflammatory pressure impinging on his brachial plexus." *Id.*

Dr. Gershwin cited the Shaikh et al. case study[64] to analogize Petitioner's case with a 46-year-old woman who developed PTS following an influenza vaccine. *Id.* The subject of the Shaikh et al. study presented "with a month's history of severe left shoulder pain[]" with acute onset "developing a few days after an influenza vaccination in the left deltoid muscle." *See* Pet'r's Ex. 91 at 1. ECF No. 72-2. Dr. Gershwin argued that, like Petitioner, the woman in the study also developed weakness soon-after the onset of pain and was subsequently diagnosed with brachial neuritis. *Id.* In an effort to further clarify the theory of causation as it relates to the flu vaccine and Petitioner's PTS, Dr. Gershwin pointed to several pieces of submitted literature explaining generally that "a number of cases of PTS following various vaccines, including the influenza vaccine, have been reported."[65] Pet'r's Ex. 90 at 1. Dr. Gershwin maintained "the flow of lymphatics as well as the response to antigenic challenges is well[-]known and anatomically explicable [to Petitioner's case]."[66] *Id.* at 2. He therefore relied on this "medically accepted" principle to conclude Petitioner's PTS was caused by the flu vaccine. *Id.*

5. Dr. Gershwin's Fourth Supplemental Expert Report

Dr. Gershwin submitted his fourth and final supplemental expert report on November 26, 2019, in response to Dr. Leist's second supplemental report. Pet'r's Ex. 96. In this report, Dr. Gershwin was quick to note that Dr. Leist's latest report "presented no new argument." *Id.* at 1. However, Dr. Gershwin highlighted that Dr. Leist relied on "irrelevant information" to argue that "the lymphadenopathy leading to compression of the brachial plexus was not listed in the prescribing information[]" for the Afluria injection, or flu vaccine. *Id.* Dr. Gershwin stated that Dr. Leist submitted a package insert for the Afluria injection "relating to the *2017–2018* formula." *Id.* (emphasis in original). He argued, this package insert is, in fact, inapplicable to Petitioner's case because Petitioner received the 2013 formula of the Afluria injection. *Id.* A comparison of the package inserts from 2013[67] and 2017–2018[68] shows the contents of the respective vaccines are "*completely different*." *Id.* (emphasis in original). Therefore, he argued, Dr. Leist's reliance on this insert is wholly irrelevant. *Id.*

Dr. Gershwin questioned Dr. Leist's assertion that the "influenza vaccine could cause lymphadenopathy leading to compression of the brachial plexus" stating this information was not listed in the prescribing information for Afluria. *Id.* He argued that both package inserts indicate "that nervous system disorders, including *neuropathy* and *GBS* have been reported."[69] *Id.* (emphasis in original). Dr. Gershwin opined that "[j]ust like GBS, [PTS] a.k.a. brachial neuritis *is*

[64] Citing Pet'r's Ex. 91, ECF No. 72-1, Shaikh M.F., et al., *Acute brachial neuritis following influenza vaccination,* BMJ CASE REPORTS 2012.
[65] Citing Pet'r's Ex. 38 at 4, ECF No. 42-6, Tsairis P., et al., *Natural History of Brachial Plexus Neuropathy: Report on 99 Patients,* ARCH. NEUROL. 1972; 27:110; *see also* Shaikh, *supra* note 64.
[66] *See generally, supra* note 63.
[67] Citing Pet'r's Ex. 97 at 5, 9, ECF No. 77-2.
[68] Citing Resp't's Ex. D-1 at 3, 5–6, ECF No. 75-2.
[69] Citing Pet'r's Ex. 97 at 10; Resp't's Ex. D-1 at 11.

a form of peripheral neuropathy." *Id.* at 2. (emphasis in original). Dr. Gershwin continued that "[i]t is readily accepted that GBS, a peripheral neuropathy, may commence after a flu vaccine almost immediately and up to [six]…to [eight] weeks after the receipt of a flu vaccine." *Id.* He compared GBS to PTS, which may also be "a table case if the symptoms began within [two]-[twenty-eight] days." *Id.* He noted that "the heralding onset symptom of pain[]" in Petitioner's case "commenced approximately [three] weeks after the receipt of his [flu] vaccine." *Id.* Based on this, Dr. Gershwin concluded that Petitioner's onset symptom of pain "fits very nicely within the time parameters" set forth for other forms of peripheral neuropathies such as GBS. *Id.*

B. Respondent's Expert, Thomas P. Leist, M.D., Ph.D.

Dr. Leist is a board-certified neurologist. Resp't's Ex. B at 1–2, ECF No. 49-4. He attended the University of Zurich, Switzerland, for his undergraduate and doctoral studies in biochemistry. *Id.* at 1. Dr. Leist also attended medical school in the United States at the University of Miami in Florida. *Id.* He then completed a residency in neurology at Cornell Medical Center/Sloan Kettering Memorial Cancer Center before becoming a senior clinical staff associate at the National Institutes of Health in Bethesda, Maryland. *Id.*

Dr. Leist currently serves as director of the Clinical Neuroimmunology Division at the Comprehensive Multiple Sclerosis Center. *Id.* He also serves as a neurology consultant for the Inglis Foundation, and as director of Hospital-based Neurology Infusion Service. *Id.* Dr. Leist is also a professor of neurology at Thomas Jefferson University in Philadelphia, Pennsylvania, where he directs the Comprehensive Multiple Sclerosis Center and the Clinical Neuroimmunology Fellowship Program. *Id.* Dr. Leist has given lectures on Multiple Sclerosis in various locations around the world, and his curriculum vitae lists numerous books, book chapters, and research papers of which he is a listed author. *Id.* at 2–11.

Dr. Leist submitted one expert report and two supplemental expert reports in this case. Resp't's Ex. A, ECF No. 49-1; Resp't's Ex. C, ECF No. 56-1; Resp't's Ex. D, ECF No. 75-1.

1. Dr. Leist's Expert Report

Dr. Leist submitted his responsive expert report on October 3, 2017, in response to Dr. Gershwin's expert report. Resp't's Ex. A. In his report, Dr. Leist described Petitioner's extensive "history of shoulder pain that reportedly increased with activity, tenderness of the lumbar and thoracic region, and foot pain." *Id.* at 5. Dr. Leist highlighted that "[t]he contemporary records document ongoing pain affecting neck and shoulder girdle and spine that had been present for years[,] and was ongoing on January 14, 2013[]" – the day he received the flu vaccine. *Id.* He also focused on the fact that to cope with this ongoing pain, Petitioner "was on long[-]term pain management with methadone, oxycodone, and cannabis[,] before as well as after January 14, 2013."[70] *Id.* He noted that Petitioner's pain, prior to and leading up to the vaccine, ranked at a "7–8 out of 10[,] to 5–6 with cannabis[.]" *Id.* Dr. Leist further noted that Petitioner described his pain as increasing during the winter but said that taking '"[one] OxyContin a day for [two] months [] helps[.]'"[71] *Id.*

[70] Citing Pet'r's Ex. 1 at 4, 7, 24, 26–27.
[71] *See id.* at 19, 26.

Next, Dr. Leist argued that Dr. Gershwin's assertion that Petitioner "d[id] not have any traumatic basis for his brachial plexitis[]" erroneously "suggests that trauma represents the only alternate cause of [PTS] besides vaccinations." *Id.* at 8. In fact, he continued, the van Alfen and van Engelen study[72] analyzed data from two-hundred and forty-six patients with PTS and showed that "[e]xercise was the second most frequently reported event[,]" whereas "[a] temporal association with trauma and vaccination were each reported by [five] individuals . . . and so was psychological stress." *Id.* He also noted that Petitioner had been "exercising vigorously and had been lifting weights when he became aware of the muscle weakness[]"[73] and had been "in the middle of a divorce in the spring of 2013[.]"[74] *Id.* He therefore argued that, in his report, Dr. Gershwin failed to consider "other preceding events associated with [PTS] that were temporally proximate in [Petitioner's] case to the onset of weakness in May 2013." *Id.*

Dr. Leist opined that the onset of Petitioner's symptoms, specifically weakness, is outside the interval expected for PTS. *Id.* at 7–8. In support of his assertion, Dr. Leist cited a case report by Weintraub and Chia[75] of a patient with "suspected brachial neuritis/[PTS] following swine flu vaccination[.]" *Id.* at 7. Dr. Leist explained that in that case, the patient experienced "paralysis of the upper extremities" approximately seven days post-vaccination and muscle atrophy within two weeks. *Id.* He then compared that finding with Petitioner's case, stating that "[n]either weakness, nor worsening symptoms, nor atrophy were present in [Petitioner's] case [until five] weeks after vaccination[.]" *Id.* Dr. Leist did concede, however, that the case report authors "d[id] not provide information beyond the temporal association of the swine flu vaccine and the observed weakness." *Id.* He also highlighted that Petitioner's flu vaccine was "distinct from the one the patient in the case report received[,]" and therefore can only be used on an informative basis. *Id.*

Dr. Leist noted that, despite previous reports to healthcare practitioners, Petitioner "reported a [two]-month history [of] weakness in the right pectoralis muscles during follow-up with [his nurse practitioner] on July 8, 2013."[76] *Id.* This interval, he argued, "would put onset of weakness into early May, or about [five] months after administration of [the] influenza vaccine on January 14, 2013[, . . . which] is well outside the time interval noted for the patient described by Weintraub and Chia[,]" who experienced paralysis of the upper extremities within a week of vaccination. *Id.* Dr. Leist also considered the time interval reported by Langmuir et al.[77] for GBS onset after receiving the swine flu vaccination. *Id.* While Dr. Leist acknowledged that Petitioner does not have GBS as a result of the swine flu vaccine, he found the comparison can "inform on a rational time interval during which [PTS] could potentially occur following [an] influenza vaccination[.]" *Id.* He noted that the five-month interval in Petitioner's case "is also well beyond the [forty-two]-day risk interval" found by Langmuir et al. for GBS. *Id.* at 8. Based on Petitioner's long history of pain and the five-month time interval between vaccination and onset of weakness,

---

[72] *See* van Alfen & van Engelen, *supra* note 56.
[73] Citing Pet'r's Ex. 1 at 30.
[74] Citing *Id.* at 26.
[75] *See* Weintraub & Chia, *supra* note 53, at 518.
[76] Citing Pet'r's Ex. 1 at 30.
[77] Citing Resp't's Ex. A-1, ECF No. 49-2, Langmuir A., et al., *An Epidemiologic And Clinical Evaluation Of Guillain-Barré Syndrome Reported In Association With The Administration of Swine Influenza Vaccines,* AM. J. EPIDMIOL. 1984; 119:841–79.

Dr. Leist opined, to a reasonable degree of medical certainty, that Petitioner did not suffer an injury related to the flu vaccine he received on January 14, 2013. *Id.* at 9.

2. Dr. Leist's Supplemental Expert Report

Dr. Leist submitted his supplemental report on February 27, 2018, in response to Dr. Gershwin's first supplemental expert report. Resp't's Ex. C. Dr. Leist reiterated his opinion that Petitioner's PTS was not caused by the flu vaccine because his weakness developed approximately five months post-vaccination, which "is beyond the time period described by Langmuir et al. for [GBS] following influenza vaccine." *Id.* at 5. He did not rely on pain as an onset symptom of PTS. *See, e.g.*, *id.* at 1–5. Dr. Leist stated that "Dr. Gershwin d[id] not provide specific mechanistic evidence that shows to a reasonable degree of certainty a link between influenza vaccine and neuralgic amyotrophy/[PTS]." *Id.*

Dr. Leist responded to criticisms and comments made by Dr. Gershwin in his first supplemental expert report. First, regarding the "factual errors" Dr. Gershwin claimed that Dr. Leist had made in his responsive expert report, Dr. Leist noted that a reading of the records shows that Petitioner "complained of neck, shoulder, and back pain prior to January 13, 2013." *Id.* at 2. Dr. Leist noted, for example, that Petitioner saw Dr. Grant on January 26, 2009, with "a history of bilateral carpal tunnel syndrome that was worse on the right than on the left and [he] had undergone bilateral carpal tunnel surgery."[78] *Id.* at 1. Dr. Leist further indicated that numerous records from Petitioner's nurse practitioner "from at least April 2010 to at least October 2015[,]" including the one from the one for January 9, 2013, state "the patient also presents with moderate back and shoulder pain . . . [but] denies numbness in the left arm and numbness in the right arm."[79] *Id.* Dr. Leist opined "[t]he specific listing of a pertinent negative, absence of numbness of either side, suggests bilateral neck and shoulder involvement." *Id.* He therefore argued that Dr. Gershwin's assertion that Petitioner's symptoms developed "exclusively on the left" prior to January 14, 2013, is not supported by the record. *Id.* at 2.

Second, in response to Dr. Gershwin's criticism of his comparison of PTS with GBS, Dr. Leist reiterated that such comparison was "introduced only to delineate a time interval based on reputable scientific information, during which an adverse event following influenza vaccine, a non-live vaccine, could be expected." *Id.* He argued that "Dr. Gershwin's statement [that] there are no 'immunological similarities between [GBS] and [PTS]' may therefore be viewed as less accurate when viewed in the context of a putative influenza vaccine[-]induced process . . . ." *Id.* Dr. Leist opined that the time interval proposed by Langmuir et al.[80] "for influenza vaccine and [GBS] represents the best available information regarding the putative timeframe between influenza vaccine and neuralgic amyotrophy/[PTS]." *Id.* He therefore argued that the "vaccine[-]induced mechanisms underlying the alleged adverse events would likely have to be significantly the same." *Id.*

Third, Dr. Leist addressed Dr. Gershwin's assertion that "'the latency time between the onset of autoimmune disease and the first appearance of autoantibodies can range from days to

[78] Citing Pet'r's Ex. 3 at 1.
[79] Citing Pet'r's Ex. 1 at 26.
[80] *See* Langmuir et al., *supra* note 77.

years[.]'" *Id.* at 3. Dr. Leist argued that "the suggestion that a prior vaccination could cause autoimmune disease even years later would have to be viewed as speculative." *Id.* He reiterated that the "vaccine-induced mechanisms underlying alleged adverse events, including [GBS and] . . . neuralgic amyotrophy/[PTS] would likely have to be significantly the same." *Id.* Thus, he continued, because no correlation between vaccination and PTS has been established, "it is not known what an appropriated timeframe for neuralgic amyotrophy/[PTS] following influenza vaccine might be." *Id.* Nonetheless, Dr. Leist argued an association between the flu vaccine and GBS, as well as acute disseminated encephalomyelitis ("ADEM") "can also be informative" as to an appropriate timeframe for PTS following a flu vaccine. *Id.* In support, Dr. Leist cited a study by Rowhani-Rahbar et al.[81] on "biologically plausible and evidence-based risk intervals of [ADEM]. . . following immunization." *Id.* Dr. Leist noted that the study authors "'concluded that two sets of risk intervals to examine the association between vaccines and ADEM would be appropriate.'" *Id.* They proposed an interval of two to forty-two days when "determining the likelihood of a role of a vaccine in develop[ing a] neurologic illness" and an interval of five to twenty-eight days "[f]or epidemiologic assessments of causality between a particular vaccine and ADEM[.]" *Id.*

Finally, Dr. Leist responded to Dr. Gershwin's statement that in Petitioner's case "'the medical records are unclear as to when the weakness commenced.'" *Id.* Dr. Leist maintained his opinion that Petitioner's onset of weakness occurred two months prior to his July 8, 2013 visit with his nurse practitioner. *Id.* at 4. He based this opinion on the fact that Petitioner saw his chiropractor on February 14, 2013, with complaints of "a one[-]week history of '*pain* in mid[-]back increased with arm use.'" *Id.* (emphasis added). He noted that Petitioner had a follow-up visit with his chiropractor on February 19, 2013, and no weakness was reported at either visit. *Id.* Dr. Leist argued that the onset of Petitioner's weakness is "outside the time window described by Langmuir et al.[82] for an immune complication following [a] non-live influenza vaccine." *Id.* Had Petitioner developed PTS as a result of the flu vaccine, Dr. Leist argued he would have experienced weakness sooner than he did. *Id.*

Dr. Leist further addressed that although Petitioner's vaccination records do not show the administration site of the flu vaccine, Dr. Ali's initial consultation notes from June 23, 2014, document that Petitioner's "weakness 'was not [in] the same area where the injection was given[.]'"[83] *Id.* This, he argued, suggests that "it is likely that the vaccine was given into the left deltoid." *Id.* Dr. Leist emphasized that the "[c]oncentration of vaccine constituents is greatest at the site of administration and this is also the site of the needle trauma." *Id.* Therefore, he argued Dr. Gershwin failed to explain how the flu vaccine "could have caused relatively immediate [PTS] in [Petitioner's] *right* when [it] was . . . likely administered into the *left* arm." *Id.* at 4–5. (emphasis added). Dr. Leist postulated that Petitioner's development of PTS in his right side despite receiving the vaccine in his left side is contradicted by Weintraub and Chia's case report,[84] which "describes a case of hand weakness within hours following administration of influenza vaccine into the same

[81] Citing Resp't's Ex. C-2, ECF No. 56-3, Rowhani-Rahbar A., et al., *Biologically Plausible and Evidence-based Risk Intervals in Immunization Safety Research*, VACCINE 2012; 31:271–77.
[82] *See* Langmuir et al., *supra* note 77.
[83] Citing Pet'r's Ex. 4 at 1.
[84] *See* Weintraub & Chia, *supra* note 53, at 518.

arm[;]" and a case report by Taras et al.,[85] which reported "onset of weakness in the same arm as the [HPV] vaccine administration within [three] days following vaccination." *Id.* at 5. As such, Dr. Leist maintained his opinion that Petitioner "did not incur an injury due to the dose of influenza vaccine he received . . . ." *Id.*

3. Dr. Leist's Second Supplemental Expert Report

Dr. Leist submitted his second supplemental expert report on October 20, 2019, in response to Dr. Gerswhin's second supplemental report. Resp't's Ex. D. In this report, Dr. Leist took issue with Dr. Gershwin's assertion that Petitioner's pain in his right shoulder blade area three weeks post-vaccination "would be consistent with irritation and pressure from expanding regional lymph nodes secondary to the vaccine." *Id.* at 1. Dr. Leist responded by arguing that "[a]ny swelling induced by influenza, a non-live vaccine, is expected to have peaked and have resolved before [three] weeks following vaccination." *Id.* As support, Dr. Leist cited the prescribing information for Afluria (2017–2018 Formula), or the flu vaccine, which "lists that significant swelling (grade [three] swelling/lump reaction) occurred in 0.1% of vaccinated individuals . . . [and] 'began within [seven] days of vaccination.'"[86] *Id.* He pointed out Dr. Gershwin's failure to provide references capable of showing sufficient "evidence that vaccines cause lymphadenopathy[87] leading to external compression of nerves and/or brachial plexus injury[,]" as Dr. Gershwin claims occurred in Petitioner's case. *Id.* Dr. Leist argued this proposed scenario is not listed in the prescribing information for Afluria. *Id.* Based on this, Dr. Leist opined that "[s]welling following vaccine administration occurs at or around the injection site[] . . .[and i]t is unlikely that influenza vaccine would have caused focal swelling in a distant limb." *Id.* at 2.

Of the references Dr. Gershwin did submit, Dr. Leist found the Shaikh et al.[88] case report to be "consistent with the opinion [he] expressed in [his] original report . . . that a relationship between [PTS] and influenza vaccine has not been established beyond a temporal association." *Id.* Dr. Leist reiterated that the authors of the Shaikh et al.[89] case report posited that "[t]he aetiology of brachial neuritis is unclear[,]" thus failing to identify a mechanism by which an influenza vaccine could cause PTS. *Id.* at 1. Dr. Leist indicated that the articles submitted by Petitioner "discuss fluid dynamics and mechanics of lymph nodes and the lymph system[, but] do not discuss or describe the effects[] . . . of vaccines on these processes."[90] *Id.* at 2. Dr. Leist concluded by expressing "[he] was [also] unable to identify peer[-]reviewed articles that describe nerve injury as a consequence of a vaccine in the manner Dr. Gershwin allege[d]." *Id.* Therefore, he maintained Petitioner's injury did not occur as a result of the influenza vaccine. *Id.*

---

[85] Citing Resp't's Ex. C-1, ECF No. 56-2, Taras J.S., et al., *Brachial Neuritis Following Quadrivalent Human Papilloma Virus (HPV) Vaccination*, HAND 2011; 6:454–56.
[86] Citing Resp't's Ex. D-1 at 6.
[87] Lymphadenopathy is defined as a "disease of the lymph nodes, usually with swelling[.] . . .It is considered to be a nonmalignant hyperimmune reaction to chronic antigenic stimulation[.]" *Dorland's* at 1083.
[88] *See* Shaikh, *supra* note 64.
[89] *See id.*
[90] *See generally, supra* note 63.

IV. Arguments in Support of a Ruling on the Record

Petitioner filed his motion for a ruling on the record on September 6, 2018. Pet'r's Mot. Petitioner argued, among other things, that he has provided sufficient evidence to show that the influenza vaccine "is the cause in fact of his PTS." *Id.* at 18. In support of his argument, Petitioner contended that he has demonstrated that pain is the onset symptom of PTS. *Id.* at 9–12. Petitioner further argued he represented a classic presentation of PTS following a flu vaccination and that his onset symptoms are consistent with those described in the medical literature. *See id*.

Petitioner argued that he satisfied the first prong of *Althen* because his expert, Dr. Gershwin, "provided a medical theory causally connecting the vaccination with the resulting PTS." *Id.* at 19. He highlighted that Dr. Gershwin explained how Petitioner's PTS "was due to an inflammatory response to the vaccination." *Id.* Petitioner characterized Dr. Gershwin's explanation of the "cytokine response that facilitated the recruiting and homing of lymphocytes[]" following the vaccination as the medical theory required to satisfy prong one of *Althen. Id.* He reiterated Dr. Gershwin's purported theory:

> examin[ing] the role of lymph node macrophages (LNMs) in the induction of the cytokine storm triggered by inactivated influenza virus vaccine . . . [wherein] LNMs undergo inflammosome-independent necrosis-like death that is reliant on MyD88 and Toll-like receptor 7 (TLR7) expression and releases pre-stored interlukin-1α (IL-1α) . . . [s]timulation of the IL-1α inflammatory pathway might therefore represent a strategy to enhance antigen presentation by LNDCs and improve the humoral response against influenza vaccines.

Id. at 20. However, Petitioner cited the Chatziandreou et al. study[91] and conceded that "[t]he mechanism by which inflammation influences the adaptive response to vaccines is not fully understood." *Id.* Nonetheless, Petitioner argued that his expert posited a medical theory causally connecting the flu vaccine and his PTS, thus satisfying prong one of *Althen*. *Id.*

Petitioner further argued that he satisfied the second prong of *Althen* because he "ha[s] treating physicians indicating that the vaccination was the cause of his issues[.]" *Id.* at 22. Petitioner cited to notes from his treating neurologist, Dr. Ali, attributing his issues to the flu vaccine. *Id.*; *see also* Pet'r's Exs. 4 at 1–2; 10 at 1. He also referred to notes from his nurse practitioner, Ray Millette, N.P., indicating an association between the flu vaccine and his injuries. Pet'r's Mot. at 22; *see also* Pet'r's Ex. 12 at 1–3. Petitioner continued that his "response to the influenza vaccine was consistent with the theories articulated, including pain and later weakness and atrophy, . . ." which constitutes further evidence that the flu vaccine caused his development of PTS. Pet'r's Mot. at 23–24.

Petitioner argued that he has also satisfied the third prong of *Althen* by establishing that Petitioner's injuries manifested within the medically acceptable timeframe for the development of PTS following a flu vaccine. *Id.* at 24. He relied on his expert's comparison of the onset of PTS

[91] Citing Pet'r's Ex. 82, ECF No. 51-3, Chatziandreou N., et al., *Macrophage death following influenza vaccination initiates the inflammatory response that promotes dendritic cell function in the draining lymph node,* CELL REPORTS 2017; 18:2427–2440.

following a tetanus-toxoid type vaccination, two to twenty-eight days, to explain that the onset of PTS following a flu vaccine would be similar. *Id.* at 25. However, Petitioner first alleged that "[t]he primary dispute in this case is *what is* the 'onset' symptoms of [PTS] (is it pain or is it weakness) and when would such onset ordinarily occur." *Id.* (emphasis in original). Petitioner argued that "the onset symptom is *pain*; and, such pain, in this case, commenced within a time period consistent with what one would expect." *Id.* (emphasis in original). Petitioner attacked Respondent's expert's comparison between the onset of GBS and PTS but nonetheless accepted it as true and maintained that the onset of Petitioner's symptoms "commenced around February 5, 2013[,] directly down the strike zone of Dr. Leist's opinion as to when one would see first onset symptoms in a GBS case." *Id.* at 26. Petitioner reasserted his opinion that "[t]he most important onset symptom [for PTS] is the pain" and concluded that the onset of his pain occurred around February 5, 2013, within Dr. Gershwin's purported timeframe described above. *Id.*

Petitioner argued that he has satisfied his burden by a preponderance of the evidence under *Althen* and that the burden therefore shifts to Respondent to prove an alternative cause for Petitioner's injuries. *Id.* at 29. He continued that Respondent must show that "the unrelated factor was the sole substantial factor in bringing about the injury." *Id.* (citing *de Bazan v. Sec'y of Health & Hum. Servs.,* 539 F.3d 1347, 1354 (Fed. Cir. 2008)). Petitioner addressed Respondent's expert's opinion that "[Petitioner's] exercise regimen or his marital dissolution may have been the cause of his PTS[,]" and vehemently disagreed. *Id.* at 30.

Respondent filed his response to Petitioner's motion for a ruling on the record on October 22, 2018. Resp't's Resp. Respondent argued that, as a preliminary matter, Petitioner must establish that his flu vaccination was administered on the right side, or alternatively, that PTS can present in the shoulder opposite from the vaccine administration. *Id.* at 9. Respondent concluded that based on the evidence, "Petitioner has failed to meet his burden to show that he received a flu vaccination in his right arm and failed to demonstrate that a flu vaccine administered in his left deltoid could result in [PTS] on his right side." *Id.* at 10.

Respondent further argued that Petitioner has failed to meet his burden under prong one of *Althen. Id.* at 11. In support of this argument, Respondent posited that "[i]n a winding and opaque paragraph, Dr. Gershwin discusse[d] generally how inflammation may factor into autoimmune disease." *Id.*; *see also* Pet'r's Ex. 23 at 3–4. However, Respondent maintained that "[t]his general statement . . . fails under *Althen* to provide a theory that applies specifically to this case . . . [and] is insufficient to meet [P]etitioner's burden of proof on *Althen* prong [one]." Pet'r's Mot. at 11–12.

Respondent also argued that Petitioner has failed to satisfy prong two of *Althen* because he has failed to establish a logical sequence of cause and effect. *Id.* at 13. Respondent indicated that the physicians' notes cited by Petitioner to support his theory of cause and effect cannot be given much weight because they are based on Petitioner's own reported history and provided more than a year after the vaccination. *Id.* at 14. Respondent further argued there are alternative causes to explain Petitioner's development of PTS, including his extensive exercise regimen and the psychological stressors of his divorce. *Id.* Such alternative causes, Respondent argued, are "closer in proximity to the onset of Petitioner's shoulder pain" and can explain his condition better than the flu vaccine. *Id.*

Respondent argued Petitioner has also failed to meet his burden under prong three of *Althen*. *Id.* at 15. Respondent indicated that Petitioner "had a long pre[-]vaccination history of chronic shoulder pain, back pain, and carpal tunnel syndrome[,]" suggesting bilateral involvement, since 2009. *Id.* at 15–16. Respondent's expert argued that this pre-vaccination history likely contributed to the complaints before and after the date of vaccination; thus, inhibiting Petitioner's ability to satisfy prong three of *Althen*. *Id.* at 16.

Respondent also responded to Petitioner's arguments regarding the relevant onset symptom of PTS – pain versus weakness. *Id.* Respondent maintained that weakness is the onset symptom of PTS following a flu vaccine and indicated that "Petitioner placed weakness onset around May 2013, or about four to five months post[-]vaccination." *See id.* Respondent argued Petitioner's onset of weakness is inconsistent with Respondent's expert's purported "[forty-two]-day risk interval reported . . . for [GBS] after vaccination with a swine flu influenza." *Id.*; *see also* Resp't's Ex. A at 8. Respondent relied on the analogy between the onset of GBS following a swine flu vaccine and the purported timeframe for the onset of weakness following a flu vaccine to argue Petitioner's onset of weakness – five months post-vaccination – is well-beyond the forty-two-day timeframe expected for the development of weakness following a vaccine. Pet'r's Mot. at 16. Therefore, Respondent concluded Petitioner has failed to establish entitlement to compensation under *Althen.*

Petitioner filed his reply to Respondent's response to his motion for a ruling on the record on November 1, 2018. Pet'r's Reply. Petitioner first argued that as a preliminary matter, he does not need to establish that the vaccine was administered in his right side, or that PTS can present in the shoulder opposite the site of vaccine administration. *Id.* at 2. Petitioner maintained that his expert's interpretation of the medical records from neurologist, Dr. Ali, referenced pain in the right shoulder region, but "[t]his was not in the same area where the injection was given." *Id.*; *see also* Pet'r's Ex. 4 at 1–2. Petitioner argued that Dr. Gershwin's opinion that "injections in either arm can produce bilateral swelling and therefore it does not matter which side received the injection" is substantiated by Petitioner's medical records and other cases in the Vaccine Program. Pet'r's Reply at 3; *see also Garner v. Sec'y of Health & Hum. Servs.*, Case No. 15-63V, 2017 WL 1713184 (Fed. Cl. Spec. Mstr. Mar. 24, 2017), *aff'd*, 133 Fed. Cl. 140 (2017).

Petitioner further replied to Respondent's assertions that he did not provide a medical or scientific theory under prong one of *Althen.* Petitioner argued that he did provide a medical theory "causally connecting the vaccination with the resulting PTS[,] . . . and Respondent's expert did not provide much of a rebuttal to Dr. Gershwin's opinion." *Id.* at 5. Petitioner repeated his previous argument and maintained that he established a theory of cause and effect because he has treating physicians' notes showing an association between the flu vaccine and PTS. *Id.* He further argued that Respondent's expert's reliance on an analogy of causation between the swine flu vaccine and the development of PTS is incorrect. *Id.* at 6. Finally, Petitioner argued that he has established an appropriate proximate temporal relationship between vaccination and injury by relying on the fact that pain is the heralding onset symptom for PTS. *Id.* at 7. He argued that Respondent mischaracterized weakness as the onset symptom for PTS, thus ignoring that the onset of Petitioner's symptoms – pain – occurred in the appropriate timeframe one would expect for the development of PTS following a flu vaccine. *Id.* at 7–9. Therefore, Petitioner maintained that all three prongs of *Althen* have been met by a preponderance of the evidence. *Id.* at 10.

V. Applicable Legal Standard

To receive compensation under the Vaccine Act, a petitioner must demonstrate either that: (1) the petitioner suffered a "Table injury" by receiving a covered vaccine and subsequently developing a listed injury within the time frame prescribed by the Vaccine Injury Table set forth at 42 U.S.C. § 300aa-14, as amended by 42 C.F.R. § 100.3; or (2) that petitioner suffered an "off-Table injury," one not listed on the Table, as a result of his receiving a covered vaccine. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C); *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Petitioner does not allege a Table injury in this case; thus, he must prove that his injury was caused-in-fact by a Table vaccine.

To establish causation-in-fact, a petitioner must demonstrate by a preponderance of the evidence that the vaccine was the cause of the injury. 42 U.S.C. § 300aa-13(a)(1)(A). A petitioner is required to prove that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321–22 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)).

In the seminal case of *Althen v. Sec'y of the Dept. of Health & Hum. Servs*, the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d 1274, 1278–79 (Fed. Cir. 2005). The *Althen* test requires petitioners to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278. To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *See id.*

A petitioner who demonstrates by a preponderance of the evidence that he suffered an injury caused by vaccination is entitled to compensation unless the respondent can demonstrate by a preponderance of the evidence that the injury was caused by factors unrelated to the vaccination. *See Althen*, 418 F.3d at 1278; *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994).

VI. Discussion

A. *Althen* Prong One

Under the first prong of *Althen*, a petitioner must offer a scientific or medical theory that answers in the affirmative the question: "can the vaccine[] at issue cause the type of injury alleged?" *See Pafford v. Sec'y of Health & Hum. Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen*, 35 F.3d at 548; *see also Andreu v. Sec'y of Health & Hum. Servs.*, 569 F. 3d 1367, 1375, 1379 (2009) (ruling that the petitioners had satisfied *Althen* prong one where their expert witness had "presented a 'biologically plausible' theory"). Such a theory

must only be "legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548–49. However, as the Federal Circuit has made clear, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322). Rather, "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Moberly*, 592 F.3d at 1322. In general, "the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde,* 746 F.3d at 1339.

Petitioner fails to meet his burden under *Althen* prong one. Petitioner's expert, Dr. Gershwin, has failed to posit a reliable theory showing that the flu vaccine can cause PTS. Petitioner argued that Dr. Gershwin "went into great detail on what happens when an inflammatory response occurs and its mechanisms[,]" thus linking Petitioner's inflammatory response to the flu vaccine. *See* Pet'r's Mot. at 19. In fact, however, Dr. Gershwin only generally describes how inflammation may factor into autoimmune responses. Dr. Gershwin does not explain how an inflammatory process is initiated by the flu vaccine specifically or how such a response leads to PTS.

In his first expert report, Dr. Gershwin stated that "[t]he vaccination produced a significant cytokine response that facilitated recruiting and homing of lymphocytes." *See* Pet'r's Ex. 23 at 3. He continued, "[r]ecruitment of white cells or leukocytes is a critical response to virtually *everything* from infection to non-specific tissue injury and in fact interplays with diseases as diverse as [RA], atherosclerosis[,] and virtually *every other* autoimmune disease." *Id.* (emphasis added). This statement is the antithesis of what is needed to satisfy Petitioner's burden to provide a theory that specifically applies to his case. Dr. Gershwin relies on an article authored by Chavakis[92] in an attempt to argue how the flu vaccine administered to Petitioner caused inflammation leading to PTS. *Id*. However, this article only generally describes the recruitment of leucocytes in inflammatory pathologies, which, as the article admits, is a "component of almost any inflammatory pathology." *See* Pet'r's Ex. 57 at 1. Dr. Gershwin's reliance on this article is misplaced, as it is vague and wholly fails to address an inflammatory response caused by the flu vaccine.

Dr. Gershwin further argued that "vaccination promotes inflammation in the draining lymph node, which is relevant to [Petitioner's] case" and can "lead to local inflammation[]" following injection. Pet'r's Ex. 80 at 3. Dr. Gershwin relied on an article by Chatziandreou et al.[93] to illustrate how vaccination initiates inflammation in the draining lymph node. *Id.* The authors of this article considered at length "the role of lymph node macrophages (LNMs) in the induction of the cytokine storm triggered by [an] inactivated influenza virus vaccine." *See* Pet'r's Ex. 82 at 1. Yet, this theory that a flu vaccine creates a "cytokine storm" far surpasses the inflammatory reaction one would expect from a flu vaccine. The authors presented "a strategy to enhance antigen presentation by lymph node-resistant dendritic cells and improve the humoral response against influenza vaccines[,]" but the article fell silent regarding the role of vaccines in the development of autoimmune diseases generally, much less PTS specifically. *Id.* at 2. In fact, the authors readily admit that "[t]he mechanism by which inflammation influences the adaptive response to vaccines

[92] *See* Chavakis, *supra* note 42, at 686–91.
[93] *See* Chatziandreou, *supra* note 91.

is not fully understood." *Id.* If the general mechanism for vaccines as a whole is not fully understood, the mechanism by which the flu vaccine causes PTS is even more conjectural. Therefore, it is difficult to give Dr. Gershwin's emphasis on this article much weight. His reliance on this article weakens Petitioner's argument that the flu vaccine caused his PTS, as it suggests the mechanism for such a connection remains tenuous and unfounded.

Dr. Gershwin also insinuates that a genetic predisposition could explain the reaction that occurred in Petitioner's case. He briefly mentions heredity as a confounding factor by stating "that genetic predisposition is critical to understanding the rare events that can occur in individuals following vaccination." *Id.* However, Petitioner has failed to present persuasive literature or further evidence to explain the role that a genetic predisposition could play in the development of PTS following a flu vaccine[94]; therefore, Dr. Gershwin's argument is unhelpful.

Due to Dr. Gershwin's continued failure to describe the flu vaccine's role in the development of Petitioner's PTS, I afforded Petitioner an additional opportunity to file a precise expert report from Dr. Gershwin describing the flu vaccine's role in the development of Petitioner's PTS. *See* Scheduling Order at 1, ECF No. 71. Instead, Petitioner submitted a supplemental report and medical literature again describing generally how PTS occurs and the body's general response to vaccinations.[95] *See* Pet'r's Exs. 92–94. This body of submitted literature failed to address my pointed question in this case – what is the mechanism by which the flu vaccine caused PTS?

Dr. Gershwin did submit one piece of medical literature describing a case study by Shaikh et al.[96] wherein the subject, a "normally fit and well" 46-year-old woman, developed PTS following a flu vaccine. *See* Pet'r's Ex. 90 at 1. However, Dr. Gershwin's reliance on this article does not advance Petitioner's case. Although the case study describes an instance where a patient developed PTS in close proximity to her receipt of the flu vaccine, the case study still fails to identify the mechanism by which this "uncommon" phenomenon occurred, thus making Dr. Gershwin's reliance on it futile. *See id.* Instead of providing a mechanism by which the flu vaccine could cause PTS, the authors of the study merely mention past reports linking the flu vaccine and PTS.[97] *See* Pet'r's Ex. 91 at 1–2. The authors do not rely on this patient's case to identify the mechanism by which the flu vaccine can lead to PTS; they use this patient's case to educate physicians on the challenges associated with diagnosing PTS and available treatment options. *Id.* at 1–2. They describe the patient's initial presentation – "a month's history of severe left shoulder pain . . .[w]ithin a week of the onset of pain, she developed left-upper-limb weakness with difficulty in performing her usual activities." *Id.* at 1. The authors note that "[t]he onset was acute, developing a few days after an influenza vaccination[,]" but they do not identify how the flu vaccine caused PTS. *Id.* Additionally, Dr. Gershwin's reliance on this article is further unavailing, as the authors state, "[b]rachial neuritis after administration of an influenza vaccination has

---

[94] *See* Pet'r's Mot. at 23. Petitioner cites to the Weintraub et al. article submitted by Respondent to support his argument that genetic predisposition is critical to the understanding of the development of PTS. *See supra* note 53, at 1. However, the article merely indicates "genetic predisposition is suggested[,]" without providing further explanation of its relevancy. *Id.*

[95] *See supra* note 63.

[96] *See* Shaikh, *supra* note 64.

[97] *See* Parsonage & Turner, *supra* note 50.

previously been reported in three publications[,] although the exact incidence is not known . . . and currently there is insufficient evidence to accept (or reject) an association." *Id.* at 1–2. Thus, Dr. Gershwin did not establish a path between the flu vaccine and the development of PTS.

Therefore, despite numerous opportunities to do so, Petitioner has been unable to provide a scientific or medical theory describing the flu vaccine's role in the development of PTS. As a result, Petitioner has failed to meet his burden to establish by a preponderance of the evidence that the flu vaccine can cause PTS. Accordingly, I find Petitioner has failed to satisfy prong one of *Althen.*

B. *Althen* Prong Two

Under the second prong of *Althen*, a petitioner must prove that the vaccine actually did cause the alleged injury in a particular case. *See Pafford*, 2004 WL 1717359, at *4; *Althen*, 418 F.3d at 1279. The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1380; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; instead, the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original). The Court in *Pafford* noted petitioners "must prove [] both that her vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the vaccination." 2004 WL 1717359, at *4 (citing *Shyface*, 165 F.3d at 1352). Nevertheless, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress . . . ." *Capizzano*, 440 F.3d at 1325–26.

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280). This is because "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Id.* In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). While a special master must consider these opinions and records, they are not "binding on the special master or court." 42 U.S.C. § 300aa-13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . ." *Id.* The record often includes "evidence of possible sources of injury" that can show alternate causes for the alleged vaccine-related injury. *See Stone v. Sec'y of Health & Hum. Servs.,* 676 F.3d 1373, 1379 (Fed. Cir. 2012).

While the parties do not dispute that Petitioner suffers from PTS, the parties do dispute whether there is preponderant evidence indicating that the administration site of Petitioner's flu vaccine was in the right arm. Respondent argued, as a preliminary matter, Petitioner must establish

he received the flu vaccine in his right side, or alternatively, that PTS can present in the shoulder opposite vaccine administration. *See* Resp't's Resp. at 9–10. In reply, Petitioner argued that the medical records, relied upon by Dr. Gershwin, and Petitioner's own accounts to treating physicians indicate the flu vaccine was administered in Petitioner's right side. Pet'r's Reply at 2. However, Respondent's arguments regarding the site of vaccine administration are immaterial to my analysis under *Althen,* as Petitioner's claim fails under the second prong of *Althen* for distinct reasons discussed herein. Nonetheless, after a review of the relevant medical records and reports, I will assume *arguendo* that Petitioner received the flu vaccine in his right arm.

Petitioner has failed to demonstrate a logical sequence of cause and effect relating to how the flu vaccine he received on January 14, 2013, caused his development of PTS. Petitioner's expert, Dr. Gershwin, provided ample literature and documentation showing that pain is the heralding event of PTS. For example, in his first expert report, Dr. Gershwin relied on an article by Smith and Bevelaqua[98] in which the authors explained that by definition, akin to the definition provided by *Dorland's*, *supra* note 3, PTS is "characterized by an abrupt onset of upper extremity pain followed by progressive neurologic deficits, including weakness, atrophy, and [] sensory abnormalities." Pet'r's Ex. 23 at 2. Dr. Gershwin also relied on the seminal study by Parsonage and Turner[99] to demonstrate "pain is the predominant presenting symptom in 90% to 95% of patients [with PTS]." Pet'r's Ex. 31 at 2. The authors of the study continued that "the duration of the pain is highly variable, ranging from several hours to months[]" and is described as "sharp," "stabbing," and "throbbing." *Id.* Dr. Gershwin cited an additional case study by van Alfen and van Engelen[100] to further support the proposition that pain is the heralding event of PTS. Pet'r's Ex. 80 at 3. The authors of this case study examined the progression and timing of onset symptoms in two hundred and forty-six patients with PTS. *See* Pet'r's Ex. 26 at 1. Of the symptoms observed, pain proved to be the most important symptom in determining the time of onset. *Id.*

Dr. Gershwin relied on Petitioner's medical records to opine that the pain Petitioner experienced three weeks post-vaccination was the onset of his PTS. Dr. Gershwin is correct that pain is the onset symptom of PTS. *See, e.g.*, Pet'r's Exs. 26 at 1, 4; 31 at 2. However, Dr. Gershwin has not adequately accounted for Petitioner's extensive pre-vaccination history of shoulder pain, albeit that Petitioner's pain originated on his left side. The medical records indicate that Petitioner's pain progressed and was, at times, bilateral. Therefore, Petitioner's pre-vaccination history is relevant to his purported theory of cause and effect. Years prior to receiving the flu vaccine, Petitioner sustained a sports-related injury. Pet. at 2; *see also* Pet'r's Ex. 3 at 1. When irritated, this injury would cause pain in his lower back and his left side. Pet. at 2. Based on the records, this injury can be attributed to Petitioner's "enjoy[ment of] early morning gym workouts which included bench pressing [three hundred and fifteen] pounds[.]" *Id.* at 1. As a result, Petitioner maintained a "weightlifter" physique. *See* Pet'r's Ex. 5 at 1. Further, he owns his own landscaping business, which requires "[s]ignificant heavy lifting" during ten to twelve-hour days, five to six days per week. Pet. at 1. In his free time, Petitioner "enjoyed hiking, biking, boating, snowboarding, [and] waterboarding[.]" *Id.*

Since January 2009, in connection with the above-referenced injury, Petitioner has been

[98] Smith & Bevelaqua, *supra* note 36.
[99] Parsonage & Turner, *supra* note 50.
[100] van Alfen & van Engelen, *supra* note 56.

treated for "very severe and chronic carpal tunnel syndromes on the right greater than left sides[,]" for which he had "bilateral carpal tunnel decompressions" with "good results." *See* Pet'r's Ex. 3 at 1. In 2010, Petitioner was "seen for moderate, aching, and throbbing shoulder pain[]" on several occasions. *See* Pet'r's Ex. 1 at 1, 4–7. Petitioner's description of his symptoms to his treating physicians during this time are akin to those described in the Parsonage and Turner article, as those symptoms relate to pain being the onset symptom of PTS. Pet'r's Ex. 31 at 2. Additionally, in 2011, Petitioner reported back and left shoulder pain that, by 2012, was aggravated by movement and lifting. *Id.* at 13, 16, 19. Petitioner's pain has forced him to significantly alter his typical activities, especially those relating to his workout routine and landscaping business. *See, e.g.,* Pet. at 4. Since 2009, Petitioner has been medicating with cannabis, methadone, and other medications, including oxycodone and OxyContin, to alleviate his severe pain. The extent of Petitioner's pain management regimen indicates that his pain was, and continues to be, of the utmost severity. Petitioner was relying on such pain management methods prior to and on the day he received the flu vaccine; therefore, it is more likely the onset of his PTS occurred prior to the flu vaccination. Indeed, the evidence indicates that it is more likely than not that the onset of Petitioner's pain and therefore PTS, could have been *years* before he received the flu vaccine in question.

Finally, despite Petitioner's treating physicians' notes documenting a temporal association between the flu vaccine and Petitioner's development of PTS, Petitioner has still failed to establish a theory of cause and effect in this case. While contemporaneous medical records and opinions of treating physicians are favored in the Program, such documentations are not always determinative. *See Capizzano*, 440 F.3d at 1326. Here, notes from neurologist, Dr. Ali, differ from other medical records from the same timeframe, in which other providers do not link the flu vaccine to Petitioner's PTS. *See, e.g.*, Pet'r's Exs. 1 at 30–40; 2 at 1, 3; 5 at 1. Instead, other medical records note the onset of symptoms as occurring at conflicting times. *See id*. For example, Petitioner's nurse practitioner's notes from April 9, 2014 attributing the flu vaccine to Petitioner's PTS were based on a new history provided by Petitioner over a year after the vaccination, a history that was not reported immediately following the vaccine. Pet'r's Ex. 1 at 40. This notation contradicts earlier statements wherein Petitioner stated he experienced pain three weeks post-vaccination. Pet'r's Ex. 2 at 1, 3. Another notation from spring 2013 indicated Petitioner just "awoke one morning with mild neck and mid[-]back pain that was extending to his right shoulder region[.]" Pet'r's Ex. 5 at 1. Therefore, the treating physicians' notations temporally associating the flu vaccine with PTS are entitled to little weight in Petitioner's case, because the association is based solely on a temporal relationship reported by Petitioner. *See* Resp't's Ex. A at 8; Pet'r's Ex. 1 at 40. Thus, such notations are not helpful and do not support Petitioner's theory that the flu vaccine caused him to develop PTS.

Overall, Petitioner has failed to establish by a preponderance of the evidence that the flu vaccine administered on January 14, 2013, caused him to develop PTS. Therefore, for the numerous reasons described above, Petitioner cannot satisfy prong two of *Althen.*

C. *Althen* Prong Three

Under the third prong of *Althen*, a petitioner must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. For example, if a petitioner's theory involves a process that takes several days to develop after vaccination, an injury that occurred within a day

of vaccination would not be temporally consistent with that theory. Conversely, if the theory is one that anticipates a rapid development of a reaction post-vaccination, the development of the alleged injury weeks or months post-vaccination would not be consistent with that theory. Causation-in-fact cannot be inferred from temporal proximity alone. *See Grant,* 956 F.2d at 1148; *Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983) ("Without more, [a] proximate temporal relationship will not support a finding of causation").

Petitioner also fails to meet his burden under *Althen* prong three. Respondent's expert, Dr. Leist, proffered that the onset of the symptom of weakness in PTS is similar to that in GBS. *See* Resp't's Ex. A at 7–8. He did so because both conditions affect the peripheral nerves. Based on this comparison, Dr. Leist concluded that there was a "[forty-two] day risk interval" for the onset of PTS symptoms, such as weakness, following a flu vaccination. *Id.* Dr. Leist, therefore, concluded that, based on the medical records, Petitioner's onset of weakness occurred approximately five months post-vaccination, around May 2013, which is well-outside the timeframe expected for onset of this injury. *Id.* Respondent therefore opined that Petitioner's onset of PTS is too temporally removed from his flu vaccination. Petitioner's expert, Dr. Gershwin, argued "there are no immunological similarities between [GBS] and [PTS]" making Dr. Leist's analogy seem needless. *See* Pet'r's Ex. 80 at 1–2. Dr. Gershwin opined that the timeframe for the onset of PTS following a flu vaccine is abrupt pain, usually within two to twenty-eight days, followed by the first signs of weakness two weeks later.[101] *Id.* at 2.

However, as I discussed above, pain, not weakness, is the heralding event of the onset of PTS in this case. Taking this into consideration, Respondent's expert's argument that the onset of Petitioner's weakness occurred outside of the purported timeframe for both GBS and PTS, while correct, is misplaced. Dr. Gershwin's argument that Petitioner has established a temporal association between the flu vaccine and the development of PTS is also unpersuasive because of Petitioner's extensive pre-vaccination history. As the onset of Petitioner's pain – the first symptom of his PTS – occurred years prior to his receipt of the flu vaccine, Petitioner has failed to establish a temporal relationship between the flu vaccine and the development of his PTS. Therefore, I find Petitioner has failed to satisfy prong three of *Althen,* thus precluding Petitioner's ability to receive compensation for his injury.

D. Alternative Causes

If a petitioner presents a prima facie case, the Federal Circuit has held that the burden of proof shifts to the government, and respondent must prove that the "'injury . . . described in the petition is due to factors unrelated to the . . . vaccine.' 42 U.S.C. § 300aa-13(a)(1)(b)." *Knudsen,* 35 F.3d at 547. Yet, a petitioner's failure to prove any element of his prima facie case mandates that the Court deny entitlement. *See id.* Under such circumstances, the burden of proof does not shift to the respondent to establish an alternate cause for the petitioner's claimed injury. *Althen,* 418 F.3d at 1278; *see also Bradley v. Sec'y of Health & Hum. Servs.,* 991 F.2d 1570, 1575 (Fed. Cir. 1993). However, in considering the reliability of a petitioner's evidence of a prima facie case, the special master may consider alternative causes for a petitioner's condition that are reasonably raised in the record, even if the respondent does not pursue a formal alternative cause argument.

[101] van Alfen & van Engelen, *supra* note 56, at 6.

Doe v. Sec'y of Health & Hum. Servs., 601 F.3d 1349, 1358 (Fed. Cir. 2010). Thus, in weighing a petitioner's case-in-chief, a special master may consider evidence that the petitioner's alleged injury could have been caused by alternative causes. *Id.* In this case, Respondent does not have a burden to prove Petitioner's injury was caused by something other than his flu vaccine, as he has not established a prima facie case of vaccine causation. *See LaLonde,* 746 F.3d at 1340. However, since Respondent has presented arguments related to alternative causes, I will consider them briefly.

Petitioner did not adequately address the alternative causes of PTS present in his history and posited by Respondent's expert, Dr. Leist. In his expert report, Dr. Leist cited to the same van Alfen and van Engelen[102] article submitted by Petitioner to explain that there are several antecedent events that have been attributed to the development of PTS. Resp't's Ex. A at 8. Of the listed events – and most pertinent to Petitioner – exercise was the "second most frequently reported event." *Id.* Among the other reported antecedent events of PTS were trauma and psychological stress. *Id.* Dr. Leist referenced both antecedent events in relation to the onset of Petitioner's PTS and noted that Petitioner's expert wholly omitted these events from his analysis. *Id.* Despite this fact, and even though Petitioner maintains that his divorce that occurred during the spring of 2013 was "amicable," it is still relevant in my consideration of alternate causes of Petitioner's development of PTS. *Id.*; *see also Garner v. Sec'y of Health & Hum. Servs.,* 2017 WL 1713184 (Fed. Cl. Spec. Mstr. Mar. 24, 2017), *aff'd*, 133 Fed. Cl. 140 (2017) (finding that alternate causes for PTS can be persuasive in establishing that a petitioner has failed to satisfy *Althen* prong two). Based on the record, there are numerous factors that could have substantially contributed to or directly caused Petitioner's PTS, including his routine and robust exercise regimen and/or other psychological stressors. It follows that Petitioner's development of PTS would have occurred even in the absence of the vaccine; thus, the vaccine cannot be the cause. *See Pafford*, 2004 WL 1717359, at *4; *Shyface*, 165 F.3d at 1352. Therefore, Petitioner cannot show the flu vaccine he received on January 14, 2013, caused his PTS, because Petitioner's onset of PTS likely occurred years prior to his receipt of the flu vaccine.

VII. Conclusion

After a careful review of the record, including Petitioner's medical records, expert reports, and accompanying literature, Petitioner has failed to prove that it is more likely than not that he suffered from a vaccine-caused injury. Accordingly, I have no choice but to **DENY** Petitioner's claim and **DISMISS** his petition.[103]

IT IS SO ORDERED.

s/ Herbrina D. Sanders
Herbrina D. Sanders
Special Master

[102] *See id*.

[103] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of a notice renouncing the right to seek review.